Clinical trial results:
A Randomized, Double-blind, Parallel-group, Placebo- and Active-controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Combinations of Solifenacin Succinate and Mirabegron Compared to Solifenacin Succinate and Mirabegron Monotherapy in the Treatment of Overactive Bladder

Summary

EudraCT number	2012-005735-91
Trial protocol	GB BE DE NL CZ HU LV SE IT EE FI SK SI DK ES LT PL GR BG
Global end of trial date	22 October 2015

Results information

Result version number	v2 (current)
This version publication date	19 July 2018
First version publication date	04 November 2016
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	178-CL-101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01972841
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Astellas Pharma Europe B.V.
Sponsor organisation address	Sylviusweg 62, Leiden, Netherlands, 2333 BE
Public contact	Clinical Trial Disclosure, Astellas Pharma Europe B.V., astellas.resultsdisclosure@astellas.com
Scientific contact	Clinical Trial Disclosure, Astellas Pharma Europe B.V., astellas.resultsdisclosure@astellas.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 October 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of 2 dose combinations of solifenacin and mirabegron (5 + 25 mg and 5 + 50 mg) compared to solifenacin (5 mg) and mirabegron (25 mg and 50 mg) monotherapy.

Protection of trial subjects:

This clinical study was written, conducted and reported in accordance with the protocol, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, and applicable local regulations, including the European Directive 2001/20/EC, on the protection of human rights, and with the ethical principles that have their origin in the Declaration of Helsinki.
Astellas ensures that the use and disclosure of protected health information (PHI) obtained during a research study complies with the federal, national and/or regional legislation related to the privacy and protection of personal information.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 November 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 5
Country: Number of subjects enrolled	Australia: 56
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Bulgaria: 116
Country: Number of subjects enrolled	Canada: 133
Country: Number of subjects enrolled	China: 118
Country: Number of subjects enrolled	Czech Republic: 184
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	Estonia: 12
Country: Number of subjects enrolled	Finland: 6
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Germany: 159
Country: Number of subjects enrolled	Greece: 1
Country: Number of subjects enrolled	Hong Kong: 4
Country: Number of subjects enrolled	Hungary: 114
Country: Number of subjects enrolled	Italy: 25

Country: Number of subjects enrolled	Latvia: 29
Country: Number of subjects enrolled	Lithuania: 55
Country: Number of subjects enrolled	Malaysia: 8
Country: Number of subjects enrolled	Mexico: 19
Country: Number of subjects enrolled	New Zealand: 16
Country: Number of subjects enrolled	Norway: 40
Country: Number of subjects enrolled	Peru: 14
Country: Number of subjects enrolled	Philippines: 20
Country: Number of subjects enrolled	Poland: 317
Country: Number of subjects enrolled	Romania: 68
Country: Number of subjects enrolled	Russian Federation: 108
Country: Number of subjects enrolled	Singapore: 17
Country: Number of subjects enrolled	Slovakia: 158
Country: Number of subjects enrolled	Slovenia: 6
Country: Number of subjects enrolled	South Africa: 36
Country: Number of subjects enrolled	Korea, Republic of: 211
Country: Number of subjects enrolled	Spain: 48
Country: Number of subjects enrolled	Sweden: 79
Country: Number of subjects enrolled	Taiwan: 8
Country: Number of subjects enrolled	Thailand: 50
Country: Number of subjects enrolled	Turkey: 5
Country: Number of subjects enrolled	Ukraine: 325
Country: Number of subjects enrolled	United Kingdom: 23
Country: Number of subjects enrolled	United States: 873
Country: Number of subjects enrolled	Netherlands: 31
Worldwide total number of subjects	3527
EEA total number of subjects	1501

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	2383
From 65 to 84 years	1134
85 years and over	10

Subject disposition

Recruitment

Recruitment details:

Participants who had symptoms of "wet" overactive bladder (OAB) (urgency, urinary frequency and urgency incontinence) for ≥ 3 months were enrolled in 435 centers in 42 countries. Eligible participants went into a single-blind, 4-week placebo run-in period and completed a micturition diary 7 days prior to each study visit.

Pre-assignment

Screening details:

A total of 6991 participants were screened, 6275 participants received placebo run-in treatment and 3527 participants were randomized into 1 of 6 treatment arms in a 1:1:1:1:2:2 ratio in the 12-week double-blind treatment period. A total of 953 participants were also enrolled in an ambulatory blood pressure monitoring (ABPM) substudy.

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants who received matching placebo once a day for 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to mirabegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received placebo to match mirabegron 25 mg or 50 mg orally once a day at the same time each day.

Investigational medicinal product name	Placebo to solifenacin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received placebo to match solifenacin 5 mg orally once a day at the same time each day.

Arm title	Mirabegron 25 mg

Arm description:

Participants who received mirabegron 25 mg once a day for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Mirabegron
Investigational medicinal product code	YM178
Other name	Myrbetriq, Myrbetric, Betanis, Betmiga
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Participants received mirabegron 25 mg orally once a day at the same time each day.

Arm title	Mirabegron 50 mg

Arm description:
Participants who received mirabegron 50 mg once a day for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Mirabegron
Investigational medicinal product code	YM178
Other name	Myrbetriq, Myrbetric, Betanis, Betmiga
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Participants received mirabegron 50 mg orally once a day at the same time each day.

Arm title	Solifenacin 5 mg

Arm description:
Participants who received solifenacin 5 mg once a day for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Solifenacin succinate
Investigational medicinal product code	YM905
Other name	Solifenacin, Vesicare, Vesikur, Vesitrim
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Participants received solifenacin succinate 5 mg orally once a day at the same time each day.

Arm title	Solifenacin 5 mg + mirabegron 25 mg

Arm description:
Participants who received solifenacin 5 mg and mirabegron 25 mg once a day for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Solifenacin succinate
Investigational medicinal product code	YM905
Other name	Solifenacin, Vesicare, Vesikur, Vesitrim
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Participants received solifenacin succinate 5 mg orally once a day at the same time each day.

Investigational medicinal product name	Mirabegron
Investigational medicinal product code	YM178
Other name	Myrbetriq, Myrbetric, Betanis, Betmiga
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Participants received mirabegron 25 mg orally once a day at the same time each day.

Arm title	Solifenacin 5 mg + mirabegron 50 mg

Arm description:
Participants who received solifenacin 5 mg and mirabegron 50 mg once a day for 12 weeks.

Arm type	Experimental

Investigational medicinal product name	Solifenacin succinate
Investigational medicinal product code	YM905
Other name	Solifenacin, Vesicare, Vesikur, Vesitrim
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received solifenacin succinate 5 mg orally once a day at the same time each day.

Investigational medicinal product name	Mirabegron
Investigational medicinal product code	YM178
Other name	Myrbetriq, Myrbetric, Betanis, Betmiga
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received mirabegron 50 mg orally once a day at the same time each day.

Number of subjects in period 1	Placebo	Mirabegron 25 mg	Mirabegron 50 mg
Started	447	441	437
Treated	444	436	433
Completed	404	397	387
Not completed	43	44	50
Randomized but never received treatment	2	5	4
Protocol violation	2	2	3
Did not have a treatment page	-	-	-
Withdrawal by participant	21	27	23
Miscellaneous	-	-	4
Adverse event	13	8	12
Lost to follow-up	4	2	4
Lack of efficacy	1	-	-

Number of subjects in period 1	Solifenacin 5 mg	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg
Started	434	885	883
Treated	432	878	871
Completed	397	802	798
Not completed	37	83	85
Randomized but never received treatment	2	6	13
Protocol violation	5	9	4
Did not have a treatment page	-	1	-
Withdrawal by participant	16	33	34
Miscellaneous	1	-	4
Adverse event	9	21	26
Lost to follow-up	2	9	3

Lack of efficacy	2	4	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants who received matching placebo once a day for 12 weeks.	
Reporting group title	Mirabegron 25 mg
Reporting group description:	
Participants who received mirabegron 25 mg once a day for 12 weeks.	
Reporting group title	Mirabegron 50 mg
Reporting group description:	
Participants who received mirabegron 50 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg
Reporting group description:	
Participants who received solifenacin 5 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg + mirabegron 25 mg
Reporting group description:	
Participants who received solifenacin 5 mg and mirabegron 25 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg + mirabegron 50 mg
Reporting group description:	
Participants who received solifenacin 5 mg and mirabegron 50 mg once a day for 12 weeks.	

Reporting group values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg
Number of subjects	447	441	437
Age categorical Units: Subjects			
Age continuous			
Randomized analysis set (RAS), comprised of all randomized participants.			
Units: years arithmetic mean standard deviation	 57.46 ± 13.2	 56.77 ± 13.46	 56.69 ± 13.28
Gender categorical			
RAS			
Units:			
Male	102	98	99
Female	345	343	338
Mean Number of Incontinence Episodes per 24 Hours			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: incontinence episodes arithmetic mean standard deviation	 3.32 ± 3.32	 3.33 ± 3.36	 3.16 ± 3.44
Mean Number of Micturitions per 24 Hours			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: micturitions arithmetic mean standard deviation	 10.9 ± 2.81	 10.79 ± 2.61	 11.14 ± 3.22

Mean Volume Voided per Micturition			
RAS; data only available for 3475 participants [440, 433, 431, 430, 873, 868].			
Units: mL			
arithmetic mean	157.53	151.79	155.36
standard deviation	± 58.53	± 60.39	± 59.7
Number of Incontinence Episodes per Week			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: incontinence episodes			
arithmetic mean	22.99	22.85	21.58
standard deviation	± 23.2	± 23.31	± 23.53
Mean Number of Urgency Incontinence Episodes per 24 Hours			
RAS; data only available for 3469 participants [441, 432, 427, 431, 872, 866]. Only participants with ≥ 1 urgency incontinence episode at baseline were included.			
Units: urgency incontinence episodes			
arithmetic mean	3.07	2.92	2.88
standard deviation	± 3.18	± 3.05	± 3.28
Number of Urgency Incontinence Episodes per Week			
RAS; data only available for 3469 participants [441, 432, 427, 431, 872, 866]. Only participants with ≥ 1 urgency incontinence episode at baseline were included.			
Units: urgency incontinence episodes			
arithmetic mean	21.25	20.03	19.73
standard deviation	± 22.2	± 21.09	± 22.43
Mean Number of Urgency Episodes (Grade 3 or 4) per 24 Hours			
RAS; data only available for 3488 participants [442, 434, 433, 432, 876, 870]. Only participants with ≥ 1 urgency episode at baseline were included.			
Units: urgency episodes			
arithmetic mean	6.66	6.35	6.58
standard deviation	± 4.02	± 3.88	± 4.83
Mean Number of Nocturia Episodes per 24 Hours			
RAS; data only available for 3002 participants [393, 366, 377, 367, 754, 745]. Only participants with ≥ 1 nocturia episode at baseline were included.			
Units: nocturia episodes			
arithmetic mean	1.57	1.53	1.59
standard deviation	± 1.04	± 1.01	± 1.08
Number of Nocturia Episodes per Week			
RAS; data only available for 3002 participants [393, 366, 377, 367, 754, 745]. Only participants with ≥ 1 nocturia episode at baseline were included.			
Units: nocturia episodes			
arithmetic mean	10.83	10.57	10.98
standard deviation	± 7.26	± 7.06	± 7.52
Mean Number of Pads Used per 24 Hours			
RAS; data only available for 2203 participants [281, 272, 270, 278, 554, 548]. Only participants with ≥ 1 pad used at baseline were included.			
Units: pads			
arithmetic mean	2.79	2.74	2.56
standard deviation	± 2.91	± 2.63	± 3.11
Number of Pads Used per Week			
RAS; data only available for 2203 participants [281, 272, 270, 278, 554, 548]. Only participants with ≥ 1 pad used at baseline were included.			
Units: pads			

arithmetic mean	19.29	18.78	17.5
standard deviation	± 20.38	± 18.21	± 21.17

Reporting group values	Solifenacin 5 mg	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg
Number of subjects	434	885	883
Age categorical Units: Subjects			
Age continuous			
Randomized analysis set (RAS), comprised of all randomized participants.			
Units: years arithmetic mean standard deviation	 57.88 ± 12.92	 56.94 ± 13.78	 57.3 ± 13.46
Gender categorical			
RAS			
Units:			
Male	92	199	199
Female	342	686	684
Mean Number of Incontinence Episodes per 24 Hours			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: incontinence episodes arithmetic mean standard deviation	 3.56 ± 3.51	 3.15 ± 3.15	 3.11 ± 3.05
Mean Number of Micturitions per 24 Hours			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: micturitions arithmetic mean standard deviation	 10.77 ± 2.64	 10.72 ± 2.85	 10.74 ± 2.35
Mean Volume Voided per Micturition			
RAS; data only available for 3475 participants [440, 433, 431, 430, 873, 868].			
Units: mL arithmetic mean standard deviation	 152.09 ± 59.57	 159.47 ± 58.15	 153.74 ± 59.38
Number of Incontinence Episodes per Week			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: incontinence episodes arithmetic mean standard deviation	 24.64 ± 24.46	 21.57 ± 21.6	 21.41 ± 21.1
Mean Number of Urgency Incontinence Episodes per 24 Hours			
RAS; data only available for 3469 participants [441, 432, 427, 431, 872, 866]. Only participants with ≥ 1 urgency incontinence episode at baseline were included.			
Units: urgency incontinence episodes arithmetic mean standard deviation	 3.21 ± 3.32	 2.79 ± 2.8	 2.76 ± 2.63
Number of Urgency Incontinence Episodes per Week			
RAS; data only available for 3469 participants [441, 432, 427, 431, 872, 866]. Only participants with ≥ 1 urgency incontinence episode at baseline were included.			

Units: urgency incontinence episodes			
arithmetic mean	22.23	19.15	18.99
standard deviation	± 23.19	± 19.26	± 18.11
Mean Number of Urgency Episodes (Grade 3 or 4) per 24 Hours			
RAS; data only available for 3488 participants [442, 434, 433, 432, 876, 870]. Only participants with ≥ 1 urgency episode at baseline were included.			
Units: urgency episodes			
arithmetic mean	6.6	6.34	6.33
standard deviation	± 3.87	± 3.72	± 3.59
Mean Number of Nocturia Episodes per 24 Hours			
RAS; data only available for 3002 participants [393, 366, 377, 367, 754, 745]. Only participants with ≥ 1 nocturia episode at baseline were included.			
Units: nocturia episodes			
arithmetic mean	1.61	1.57	1.54
standard deviation	± 0.95	± 1.06	± 0.97
Number of Nocturia Episodes per Week			
RAS; data only available for 3002 participants [393, 366, 377, 367, 754, 745]. Only participants with ≥ 1 nocturia episode at baseline were included.			
Units: nocturia episodes			
arithmetic mean	11.13	10.82	10.62
standard deviation	± 6.6	± 7.38	± 6.74
Mean Number of Pads Used per 24 Hours			
RAS; data only available for 2203 participants [281, 272, 270, 278, 554, 548]. Only participants with ≥ 1 pad used at baseline were included.			
Units: pads			
arithmetic mean	2.84	2.44	2.55
standard deviation	± 3.08	± 2.56	± 2.37
Number of Pads Used per Week			
RAS; data only available for 2203 participants [281, 272, 270, 278, 554, 548]. Only participants with ≥ 1 pad used at baseline were included.			
Units: pads			
arithmetic mean	19.62	16.72	17.5
standard deviation	± 21.39	± 17.58	± 16.34

Reporting group values	Total		
Number of subjects	3527		
Age categorical			
Units: Subjects			

Age continuous			
Randomized analysis set (RAS), comprised of all randomized participants.			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
RAS			
Units:			
Male	789		
Female	2738		

Mean Number of Incontinence Episodes per 24 Hours			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: incontinence episodes arithmetic mean standard deviation	- -		
Mean Number of Micturitions per 24 Hours			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: micturitions arithmetic mean standard deviation	- -		
Mean Volume Voided per Micturition			
RAS; data only available for 3475 participants [440, 433, 431, 430, 873, 868].			
Units: mL arithmetic mean standard deviation	- -		
Number of Incontinence Episodes per Week			
RAS; data only available for 3490 participants [444, 434, 433, 432, 877, 870].			
Units: incontinence episodes arithmetic mean standard deviation	- -		
Mean Number of Urgency Incontinence Episodes per 24 Hours			
RAS; data only available for 3469 participants [441, 432, 427, 431, 872, 866]. Only participants with ≥ 1 urgency incontinence episode at baseline were included.			
Units: urgency incontinence episodes arithmetic mean standard deviation	- -		
Number of Urgency Incontinence Episodes per Week			
RAS; data only available for 3469 participants [441, 432, 427, 431, 872, 866]. Only participants with ≥ 1 urgency incontinence episode at baseline were included.			
Units: urgency incontinence episodes arithmetic mean standard deviation	- -		
Mean Number of Urgency Episodes (Grade 3 or 4) per 24 Hours			
RAS; data only available for 3488 participants [442, 434, 433, 432, 876, 870]. Only participants with ≥ 1 urgency episode at baseline were included.			
Units: urgency episodes arithmetic mean standard deviation	- -		
Mean Number of Nocturia Episodes per 24 Hours			
RAS; data only available for 3002 participants [393, 366, 377, 367, 754, 745]. Only participants with ≥ 1 nocturia episode at baseline were included.			
Units: nocturia episodes arithmetic mean standard deviation	- -		
Number of Nocturia Episodes per Week			
RAS; data only available for 3002 participants [393, 366, 377, 367, 754, 745]. Only participants with ≥ 1 nocturia episode at baseline were included.			
Units: nocturia episodes arithmetic mean			

standard deviation	-		
Mean Number of Pads Used per 24 Hours			
RAS; data only available for 2203 participants [281, 272, 270, 278, 554, 548]. Only participants with ≥ 1 pad used at baseline were included.			
Units: pads arithmetic mean standard deviation	- -		
Number of Pads Used per Week			
RAS; data only available for 2203 participants [281, 272, 270, 278, 554, 548]. Only participants with ≥ 1 pad used at baseline were included.			
Units: pads arithmetic mean standard deviation	- -		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants who received matching placebo once a day for 12 weeks.	
Reporting group title	Mirabegron 25 mg
Reporting group description:	
Participants who received mirabegron 25 mg once a day for 12 weeks.	
Reporting group title	Mirabegron 50 mg
Reporting group description:	
Participants who received mirabegron 50 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg
Reporting group description:	
Participants who received solifenacin 5 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg + mirabegron 25 mg
Reporting group description:	
Participants who received solifenacin 5 mg and mirabegron 25 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg + mirabegron 50 mg
Reporting group description:	
Participants who received solifenacin 5 mg and mirabegron 50 mg once a day for 12 weeks.	

Primary: Change from Baseline to End of Treatment (EoT) in Mean Number of Incontinence Episodes per 24 Hours

End point title	Change from Baseline to End of Treatment (EoT) in Mean Number of Incontinence Episodes per 24 Hours
End point description:	
An incontinence episode was defined as the complaint of any involuntary leakage of urine. The mean number of incontinence episodes per 24 hours was calculated from data recorded by the participant per day on valid diary days during the 7-day micturition diary period. The analysis population was the Full Analysis Set (FAS), which was comprised of all randomized participants who took ≥ 1 dose of double-blind treatment, reported ≥ 1 micturition in the baseline diary and ≥ 1 micturition postbaseline, reported ≥ 1 incontinence episode in the baseline diary and excluded participants from one site. Last observation carried forward (LOCF) was used for EoT.	
End point type	Primary
End point timeframe:	
Baseline and EoT (up to 12 weeks)	

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	412	409	406	413
Units: incontinence episodes				
least squares mean (standard error)	-1.34 (± 0.10)	-1.70 (± 0.10)	-1.76 (± 0.10)	-1.79 (± 0.10)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	823	816		
Units: incontinence episodes				
least squares mean (standard error)	-2.04 (± 0.07)	-1.98 (± 0.07)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1236
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.072 [2]
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	-0.01
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[1] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.
[2] - Nominal p-value

Statistical analysis title	Difference vs. Solifenacin 5 mg (2)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1229
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.033
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.44
upper limit	0.04
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[3] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.

Statistical analysis title	Difference vs. Mirabegron 25 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 25 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1232
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0.001 [5]
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.58
upper limit	-0.1
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[4] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.

[5] - Nominal p-value

Statistical analysis title	Difference vs. Mirabegron 50 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 50 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1222
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.052
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	0.01
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[6] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.

Primary: Change from Baseline to EoT in Mean Number of Micturitions per 24 Hours

End point title	Change from Baseline to EoT in Mean Number of Micturitions per 24 Hours

End point description:

A micturition was defined as any voluntary micturition (excluding incontinence only episodes). The mean number of micturitions per 24 hours was calculated from data recorded by the participant per day on valid diary days during the 7-day micturition diary period. The analysis population was the FAS. LOCF was used for EoT.

End point type	Primary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	412	409	406	413
Units: micturitions				
least squares mean (standard error)	-1.64 (± 0.12)	-2.00 (± 0.12)	-2.03 (± 0.12)	-2.20 (± 0.12)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	823	816		
Units: micturitions				
least squares mean (standard error)	-2.49 (± 0.08)	-2.59 (± 0.08)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1236
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.04 [8]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.57
upper limit	-0.01
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[7] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.
[8] - Nominal p-value

Statistical analysis title	Difference vs. Solifenacin 5 mg (2)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1229
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.006 [10]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.67
upper limit	-0.11
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[9] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.

[10] - Nominal p-value

Statistical analysis title	Difference vs. Mirabegron 25 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 25 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1232
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	= 0.001 [12]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	-0.21
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[11] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.
[12] - Nominal p-value

Statistical analysis title	Difference vs. Mirabegron 50 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 50 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1222
Analysis specification	Pre-specified
Analysis type	superiority[13]
P-value	< 0.001 [14]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.84
upper limit	-0.28
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[13] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.

[14] - Nominal p-value

Secondary: Change from Baseline to EoT in Mean Volume Voided per Micturition

End point title	Change from Baseline to EoT in Mean Volume Voided per Micturition

End point description:

The mean volume voided per micturition was calculated from the data recorded by the participant during 3 consecutive days with volume measurements during the 7-day micturition diary period. The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	413	407	408	411
Units: mL				
least squares mean (standard error)	8.44 (± 2.55)	13.32 (± 2.57)	21.99 (± 2.57)	30.99 (± 2.56)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	821	821		
Units: mL				
least squares mean (standard error)	34.84 (± 1.81)	39.73 (± 1.81)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg

Number of subjects included in analysis	1232
Analysis specification	Pre-specified
Analysis type	superiority[15]
P-value	= 0.219 [16]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	3.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.29
upper limit	10
Variability estimate	Standard error of the mean
Dispersion value	3.13

Notes:

[15] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.
[16] - Nominal p-value

Statistical analysis title	Difference vs. Solifenacin 5 mg (2)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1232
Analysis specification	Pre-specified
Analysis type	superiority[17]
P-value	= 0.005 [18]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	8.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.61
upper limit	14.89
Variability estimate	Standard error of the mean
Dispersion value	3.13

Notes:

[17] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.
[18] - Nominal p-value

Statistical analysis title	Difference vs. Mirabegron 25 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 25 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg

Number of subjects included in analysis	1228
Analysis specification	Pre-specified
Analysis type	superiority[19]
P-value	< 0.001 [20]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	21.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.35
upper limit	27.68
Variability estimate	Standard error of the mean
Dispersion value	3.14

Notes:

[19] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.
[20] - Nominal p-value

Statistical analysis title	Difference vs. Mirabegron 50 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 50 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1229
Analysis specification	Pre-specified
Analysis type	superiority[21]
P-value	< 0.001 [22]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	17.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.58
upper limit	23.9
Variability estimate	Standard error of the mean
Dispersion value	3.14

Notes:

[21] - Adjustment for multiplicity across primary and the first secondary endpoint as well as across the 2 combination doses was made using a sequential Bonferroni-based testing procedure. No adjustment for multiplicity was needed for testing combination therapy vs. its 2 monotherapy components.
[22] - Nominal p-value

Secondary: Change from Baseline to EoT in OAB Questionnaire (OAB-q) Symptom Bother Score

End point title	Change from Baseline to EoT in OAB Questionnaire (OAB-q) Symptom Bother Score

End point description:

The OAB-q was a self-reported questionnaire with items relating to symptom bother and health-related quality of life (HRQoL). The symptom bother portion consisted of 8 items, rated on a 6-point Likert scale

(1 through 6). The total symptom bother score was calculated from the 8 answers and then transformed to range from 0 (least severity) to 100 (worst severity). A negative change from baseline indicated an improvement. The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	400	392	398	399
Units: units on a scale				
least squares mean (standard error)	-19.45 (± 0.98)	-23.93 (± 0.99)	-26.14 (± 0.98)	-26.44 (± 0.98)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	800	795		
Units: units on a scale				
least squares mean (standard error)	-31.06 (± 0.69)	-32.24 (± 0.70)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1199
Analysis specification	Pre-specified
Analysis type	superiority[23]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-4.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.98
upper limit	-2.27

Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[23] - No adjustment for multiplicity was made for this comparison.

Statistical analysis title	Difference vs. Solifenacin 5 mg (2)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1194
Analysis specification	Pre-specified
Analysis type	superiority[24]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.17
upper limit	-3.44
Variability estimate	Standard error of the mean
Dispersion value	1.21

Notes:

[24] - No adjustment for multiplicity was made for this comparison.

Statistical analysis title	Difference vs. Mirabegron 25 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 25 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1192
Analysis specification	Pre-specified
Analysis type	superiority[25]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-7.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.5
upper limit	-4.76
Variability estimate	Standard error of the mean
Dispersion value	1.21

Notes:

[25] - No adjustment for multiplicity was made for this comparison.

Statistical analysis title	Difference vs. Mirabegron 50 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 50 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1193
Analysis specification	Pre-specified
Analysis type	superiority[26]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.46
upper limit	-3.74
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[26] - No adjustment for multiplicity was made for this comparison.

Secondary: Change from Baseline to EoT in Treatment Satisfaction-Visual Analogue Scale (TS-VAS)

End point title	Change from Baseline to EoT in Treatment Satisfaction-Visual Analogue Scale (TS-VAS)

End point description:

The TS-VAS was a visual analogue scale which asked participants to rate their satisfaction with the treatment by placing a vertical mark on a line that runs from 0 (No, not at all) on the left to 10 (Yes, completely) on the right. A positive change from baseline indicated improvement. The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	399	391	398	399
Units: units on a scale				
least squares mean (standard error)	1.42 (± 0.11)	2.16 (± 0.11)	2.18 (± 0.11)	2.28 (± 0.11)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	798	794		
Units: units on a scale				
least squares mean (standard error)	2.53 (± 0.08)	2.55 (± 0.08)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1197
Analysis specification	Pre-specified
Analysis type	superiority[27]
P-value	= 0.077
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.03
upper limit	0.52
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[27] - No adjustment for multiplicity was made for this comparison.

Statistical analysis title	Difference vs. Solifenacin 5 mg (2)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1193
Analysis specification	Pre-specified
Analysis type	superiority[28]
P-value	= 0.05
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	0.27

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.55
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[28] - No adjustment for multiplicity was made for this comparison.

Statistical analysis title	Difference vs. Mirabegron 25 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 25 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1189
Analysis specification	Pre-specified
Analysis type	superiority[29]
P-value	= 0.008
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.65
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[29] - No adjustment for multiplicity was made for this comparison.

Statistical analysis title	Difference vs. Mirabegron 50 mg

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 50 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (< 65, ≥ 65 years), previous overactive bladder medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1192
Analysis specification	Pre-specified
Analysis type	superiority[30]
P-value	= 0.007
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	0.37

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.65
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[30] - No adjustment for multiplicity was made for this comparison.

Secondary: Number of Incontinence Episodes at Weeks 4, 8, 12 and EoT

End point title	Number of Incontinence Episodes at Weeks 4, 8, 12 and EoT

End point description:

The number of incontinence episodes was calculated as the total number of incontinence episodes on valid diary days recorded during the 7-day micturition diary period. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EOT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: incontinence episodes				
least squares mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	18.09 (± 1.17)	15.65 (± 1.08)	12.90 (± 1.06)	15.31 (± 1.11)
Week 8 [N=397, 385, 386, 386, 784, 769]	14.45 (± 1.12)	12.84 (± 1.05)	11.31 (± 1.09)	12.19 (± 1.06)
Week 12 [N=374, 369, 369, 379, 754, 750]	14.06 (± 1.17)	10.60 (± 0.98)	9.50 (± 0.98)	11.25 (± 1.03)
Eot [N=412, 409, 406, 413, 823, 816]	13.70 (± 1.08)	11.19 (± 0.95)	9.79 (± 0.94)	11.21 (± 0.98)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: incontinence episodes				
least squares mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	12.51 (± 0.67)	11.44 (± 0.70)		
Week 8 [N=397, 385, 386, 386, 784, 769]	9.70 (± 0.65)	9.33 (± 0.68)		
Week 12 [N=374, 369, 369, 379, 754, 750]	7.62 (± 0.57)	8.21 (± 0.68)		
Eot [N=412, 409, 406, 413, 823, 816]	8.02 (± 0.55)	8.18 (± 0.64)		

Statistical analyses

Statistical analysis title	Rate ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, ≥65 years), geographic region and previous OAB medication (yes, no) as factors, log(number of incontinence episodes used divided by number of valid diary days) at baseline included as a covariate and number of valid diary days at EoT as the offset variable.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.135
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.04
Variability estimate	Standard error of the mean
Dispersion value	0.09

Statistical analysis title	Rate ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, ≥65 years), geographic region and previous OAB medication (yes, no) as factors, log(number of incontinence episodes used divided by number of valid diary days) at baseline included as a covariate and number of valid diary days at EoT as the offset variable.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.282
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.09

Variability estimate	Standard error of the mean
Dispersion value	0.09

Statistical analysis title	Rate ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, ≥65 years), geographic region and previous OAB medication (yes, no) as factors, log(number of incontinence episodes used divided by number of valid diary days) at baseline included as a covariate and number of valid diary days at EoT as the offset variable.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.85
Variability estimate	Standard error of the mean
Dispersion value	0.09

Statistical analysis title	Rate ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, ≥65 years), geographic region and previous OAB medication (yes, no) as factors, log(number of incontinence episodes used divided by number of valid diary days) at baseline included as a covariate and number of valid diary days at EoT as the offset variable.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.172
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.06
Variability estimate	Standard error of the mean
Dispersion value	0.1

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Number of Incontinence Episodes

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Number of Incontinence Episodes

End point description:

The number of incontinence episodes was calculated as the total number of incontinence episodes on valid diary days recorded during the 7-day micturition diary period. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: incontinence episodes				
least squares mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	-5.23 (± 0.66)	-7.59 (± 0.66)	-8.99 (± 0.67)	-8.92 (± 0.67)
Week 8 [N=397, 385, 386, 386, 784, 769]	-8.79 (± 0.71)	-10.57 (± 0.72)	-10.97 (± 0.72)	-11.89 (± 0.72)
Week 12 [N=374, 369, 369, 379, 754, 750]	-9.05 (± 0.72)	-12.33 (± 0.72)	-12.58 (± 0.72)	-12.75 (± 0.71)
EoT [N=412, 409, 406, 413, 823, 816]	-9.42 (± 0.68)	-11.93 (± 0.68)	-12.39 (± 0.68)	-12.65 (± 0.68)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	823	816		
Units: incontinence episodes				
least squares mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	-9.62 (± 0.47)	-10.51 (± 0.47)		
Week 8 [N=397, 385, 386, 386, 784, 769]	-12.53 (± 0.50)	-12.78 (± 0.51)		
Week 12 [N=374, 369, 369, 379, 754, 750]	-14.50 (± 0.51)	-13.94 (± 0.51)		
EoT [N=412, 409, 406, 413, 823, 816]	-14.29 (± 0.48)	-13.98 (± 0.48)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.074
Method	Stratified rank ANCOVA
Parameter estimate	least squares mean difference
Point estimate	-1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.27
upper limit	-0.01
Variability estimate	Standard error of the mean
Dispersion value	0.83

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the solifenacin 5 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1231
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.025
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.96
upper limit	0.3
Variability estimate	Standard error of the mean
Dispersion value	0.83

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 25 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1233
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Stratified rank ANCOVA
Parameter estimate	least square mean difference
Point estimate	-2.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	-0.73
Variability estimate	Standard error of the mean
Dispersion value	0.83

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the mirabegron 50 mg monotherapy group from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1227
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.024
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.23
upper limit	0.05
Variability estimate	Standard error of the mean
Dispersion value	0.84

Secondary: Change from Baseline to Weeks 4, 8 and 12 in Mean Number of Incontinence Episodes per 24 Hours

End point title	Change from Baseline to Weeks 4, 8 and 12 in Mean Number of Incontinence Episodes per 24 Hours

End point description:

The mean number of incontinence episodes per 24 hours was calculated from data recorded by the

participant per day on valid diary days during the 7-day micturition diary period. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: incontinence episodes				
least squares mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	-0.74 (± 0.10)	-1.07 (± 0.10)	-1.24 (± 0.10)	-1.24 (± 0.10)
Week 8 [N=397, 385, 386, 386, 784, 769]	-1.20 (± 0.10)	-1.51 (± 0.10)	-1.57 (± 0.10)	-1.66 (± 0.10)
Week 12 [N=374, 369, 369, 379, 754, 750]	-1.30 (± 0.11)	-1.76 (± 0.11)	-1.81 (± 0.11)	-1.80 (± 0.10)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: incontinence episodes				
least squares mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	-1.38 (± 0.07)	-1.50 (± 0.07)		
Week 8 [N=397, 385, 386, 386, 784, 769]	-1.79 (± 0.07)	-1.84 (± 0.07)		
Week 12 [N=374, 369, 369, 379, 754, 750]	-2.08 (± 0.07)	-1.98 (± 0.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 8 and 12 in Mean Number of Micturitions per 24 Hours

End point title	Change from Baseline to Weeks 4, 8 and 12 in Mean Number of Micturitions per 24 Hours

End point description:

The mean number of micturitions per 24 hours was calculated from data recorded by the participant per day on valid diary days during the 7-day micturition diary period. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: micturitions				
least squares mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	-1.02 (± 0.11)	-1.46 (± 0.11)	-1.44 (± 0.11)	-1.39 (± 0.11)
Week 8 [N=397, 385, 386, 386, 784, 769]	-1.43 (± 0.11)	-1.95 (± 0.12)	-1.89 (± 0.12)	-1.84 (± 0.12)
Week 12 [N=374, 369, 369, 379, 754, 750]	-1.51 (± 0.12)	-2.01 (± 0.12)	-2.03 (± 0.12)	-2.22 (± 0.12)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: micturitions				
least squares mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	-1.67 (± 0.08)	-1.91 (± 0.08)		
Week 8 [N=397, 385, 386, 386, 784, 769]	-2.23 (± 0.08)	-2.42 (± 0.08)		
Week 12 [N=374, 369, 369, 379, 754, 750]	-2.47 (± 0.08)	-2.60 (± 0.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 8 and 12 in Mean Volume Voided per Micturition

End point title	Change from Baseline to Weeks 4, 8 and 12 in Mean Volume Voided per Micturition

End point description:

The mean volume voided per micturition was calculated from the data recorded by the participant during 3 consecutive days with volume measurements during the 7-day micturition diary period. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: mL				
least squares mean (standard error)				
Week 4 [N=403, 398, 399, 395, 798, 802]	6.95 (± 2.13)	10.08 (± 2.14)	15.52 (± 2.14)	24.23 (± 2.15)
Week 8 [N=395, 382, 380, 387, 770, 771]	9.00 (± 2.48)	10.96 (± 2.52)	17.73 (± 2.53)	27.55 (± 2.50)
Week 12 [N=373, 362, 364, 378, 750, 750]	8.70 (± 2.70)	12.88 (± 2.74)	22.40 (± 2.73)	31.89 (± 2.68)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: mL				
least squares mean (standard error)				
Week 4 [N=403, 398, 399, 395, 798, 802]	25.54 (± 1.51)	28.99 (± 1.51)		
Week 8 [N=395, 382, 380, 387, 770, 771]	32.94 (± 1.78)	36.51 (± 1.77)		
Week 12 [N=373, 362, 364, 378, 750, 750]	35.52 (± 1.90)	41.28 (± 1.90)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to EoT in Corrected Micturition Frequency

End point title	Change from Baseline to EoT in Corrected Micturition Frequency

End point description:

Corrected micturition frequency was defined as the mean number of micturitions per 24 hours that participants had at end of treatment if their fluid intake had remained unchanged since baseline. The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	412	409	406	413
Units: micturitions				
least squares mean (standard error)	0.15 (± 0.24)	-0.17 (± 0.24)	-0.97 (± 0.24)	-1.28 (± 0.24)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	823	816		
Units: micturitions				
least squares mean (standard error)	-1.10 (± 0.17)	-1.52 (± 0.17)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1236
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.52
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.39
upper limit	0.76
Variability estimate	Standard error of the mean
Dispersion value	0.29

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline mean number of

micturitions per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.413
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.82
upper limit	0.34
Variability estimate	Standard error of the mean
Dispersion value	0.29

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1232
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	-0.34
Variability estimate	Standard error of the mean
Dispersion value	0.29

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1222
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.06
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.13
upper limit	0.02
Variability estimate	Standard error of the mean
Dispersion value	0.3

Secondary: Number of Urgency Incontinence Episodes at Weeks 4, 8, 12 and EOT

End point title	Number of Urgency Incontinence Episodes at Weeks 4, 8, 12 and EOT

End point description:

An urgency incontinence episode was defined as the involuntary leakage of urine accompanied by or immediately preceded by urgency. The number of urgency incontinence episodes was number of times a participant recorded an urgency incontinence episode during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. Only participants with ≥ 1 urgency incontinence episode at baseline were included in the analysis. N is the number of participants analyzed with data available at each time point. LOCF was used for EOT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: urgency incontinence episodes				
least squares mean (standard error)				
Week 4 [N=403, 404, 396, 401, 813, 806]	15.76 (± 1.10)	13.36 (± 0.99)	11.46 (± 1.00)	13.19 (± 1.06)
Week 8 [N=394, 383, 380, 385, 780, 765]	12.77 (± 1.07)	10.65 (± 0.94)	10.09 (± 1.02)	10.41 (± 1.00)
Week 12 [N=371, 367, 363, 378, 750, 746]	12.00 (± 1.09)	8.84 (± 0.89)	8.32 (± 0.94)	9.29 (± 0.96)
EOT [N=409, 407, 400, 412, 819, 812]	11.69 (± 1.00)	9.37 (± 0.86)	8.63 (± 0.89)	9.29 (± 0.91)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: urgency incontinence episodes				
least squares mean (standard error)				
Week 4 [N=403, 404, 396, 401, 813, 806]	10.22 (± 0.58)	9.33 (± 0.58)		
Week 8 [N=394, 383, 380, 385, 780, 765]	7.58 (± 0.53)	7.31 (± 0.54)		
Week 12 [N=371, 367, 363, 378, 750, 746]	5.86 (± 0.46)	6.27 (± 0.49)		
EOT [N=409, 407, 400, 412, 819, 812]	6.25 (± 0.45)	6.15 (± 0.47)		

Statistical analyses

Statistical analysis title	Rate ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Rate ratio of number of urgency incontinence episodes during the 7-day diary bet. the given combination group & the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65,≥ 65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of urgency incontinence episodes used divided by number of valid diary days) included as a covariate & postbaseline number of valid diary days as offset variable.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.11
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.04
Variability estimate	Standard error of the mean
Dispersion value	0.1

Statistical analysis title	Rate ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Rate ratio of number of urgency incontinence episodes during the 7-day diary bet. the given combination group & the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65,≥ 65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of urgency incontinence episodes used divided by number of valid diary days) included as a covariate & postbaseline number of valid diary days as offset variable.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.288
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.1
Variability estimate	Standard error of the mean
Dispersion value	0.1

Statistical analysis title	Rate ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Rate ratio of number of urgency incontinence episodes during the 7-day diary bet. the given combination group & the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65,≥ 65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of urgency incontinence episodes used divided by number of valid diary days) included as a covariate & postbaseline number of valid diary days as offset variable.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.79
Variability estimate	Standard error of the mean
Dispersion value	0.1

Statistical analysis title	Rate ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Rate ratio of number of urgency incontinence episodes during the 7-day diary bet. the given combination group & the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65,≥ 65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of urgency incontinence episodes used divided by number of valid diary days) included as a covariate & postbaseline number of valid diary days as offset variable.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.084
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.02
Variability estimate	Standard error of the mean
Dispersion value	0.1

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Number of Urgency Incontinence Episodes

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Number of Urgency Incontinence Episodes

End point description:

The number of urgency incontinence episodes was number of times a participant recorded an urgency incontinence episode during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with ≥ 1 urgency incontinence episode at baseline were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: urgency incontinence episodes				
least squares mean (standard error)				
Week 4 [N=403, 404, 396, 401, 813, 806]	-5.49 (± 0.63)	-7.07 (± 0.63)	-8.39 (± 0.63)	-8.53 (± 0.63)
Week 8 [N=394, 383, 380, 385, 780, 765]	-8.30 (± 0.66)	-9.93 (± 0.67)	-10.07 (± 0.67)	-11.10 (± 0.67)
Week 12 [N=371, 367, 363, 378, 750, 746]	-8.96 (± 0.65)	-11.39 (± 0.66)	-11.66 (± 0.66)	-12.10 (± 0.65)
EoT [N=409, 407, 400, 412, 819, 812]	-9.26 (± 0.62)	-11.03 (± 0.62)	-11.44 (± 0.62)	-12.03 (± 0.62)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: urgency incontinence episodes				
least squares mean (standard error)				
Week 4 [N=403, 404, 396, 401, 813, 806]	-9.44 (± 0.44)	-10.23 (± 0.44)		
Week 8 [N=394, 383, 380, 385, 780, 765]	-12.18 (± 0.47)	-12.38 (± 0.47)		
Week 12 [N=371, 367, 363, 378, 750, 746]	-13.87 (± 0.46)	-13.53 (± 0.46)		
EoT [N=409, 407, 400, 412, 819, 812]	-13.64 (± 0.44)	-13.64 (± 0.44)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.114
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.09
upper limit	-0.13
Variability estimate	Standard error of the mean
Dispersion value	0.76

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	-0.13
Variability estimate	Standard error of the mean
Dispersion value	0.76

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-2.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.09
upper limit	-1.12
Variability estimate	Standard error of the mean
Dispersion value	0.76

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-2.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	-0.71
Variability estimate	Standard error of the mean
Dispersion value	0.76

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Mean Number of Urgency Incontinence Episodes per 24 Hours

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Mean Number of Urgency Incontinence Episodes per 24 Hours

End point description:

The mean number of urgency incontinence episodes was calculated from data recorded by the participant per day on valid diary days during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with ≥ 1 urgency incontinence episode at baseline were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: urgency incontinence episodes				
least squares mean (standard error)				
Week 4 [N=403, 404, 396, 401, 813, 806]	-0.78 (± 0.09)	-1.00 (± 0.09)	-1.15 (± 0.09)	-1.19 (± 0.09)
Week 8 [N=394, 383, 380, 385, 780, 765]	-1.15 (± 0.10)	-1.43 (± 0.10)	-1.44 (± 0.10)	-1.56 (± 0.10)
Week 12 [N=371, 367, 363, 378, 750, 746]	-1.29 (± 0.10)	-1.63 (± 0.10)	-1.67 (± 0.10)	-1.72 (± 0.10)
EoT [N=409, 407, 400, 412, 819, 812]	-1.33 (± 0.09)	-1.58 (± 0.09)	-1.62 (± 0.09)	-1.71 (± 0.09)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: urgency incontinence episodes				
least squares mean (standard error)				
Week 4 [N=403, 404, 396, 401, 813, 806]	-1.35 (± 0.06)	-1.47 (± 0.06)		
Week 8 [N=394, 383, 380, 385, 780, 765]	-1.74 (± 0.07)	-1.79 (± 0.07)		
Week 12 [N=371, 367, 363, 378, 750, 746]	-1.99 (± 0.07)	-1.93 (± 0.07)		
EoT [N=409, 407, 400, 412, 819, 812]	-1.95 (± 0.06)	-1.94 (± 0.06)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.134
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	-0.02
Variability estimate	Standard error of the mean
Dispersion value	0.11

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.043
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.45
upper limit	-0.02
Variability estimate	Standard error of the mean
Dispersion value	0.11

Statistical analysis title	Difference vs. Mirabegron 25 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.59
upper limit	-0.15
Variability estimate	Standard error of the mean
Dispersion value	0.11

Statistical analysis title	Difference vs. Mirabegron 25 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	Stratified rank ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	-0.1
Variability estimate	Standard error of the mean
Dispersion value	0.11

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Mean Number of Urgency Episodes (Grade 3 or 4) per 24 Hours

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Mean Number of Urgency Episodes (Grade 3 or 4) per 24 Hours

End point description:

An urgency episode was a complaint of a sudden, compelling desire to pass urine, which was difficult to defer; it was recorded when a micturition or incontinence episode was recorded and the severity of urinary urgency recorded was 3 (severe urgency) or 4 (urgency incontinence) according to the Patient Perception of Intensity of Urgency Scale (PPIUS). The mean number of urgency episodes was calculated from data recorded by the participant per day on valid diary days during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with ≥ 1 urgency episode at baseline were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: urgency episodes				
least squares mean (standard error)				
Week 4 [N=405, 406, 402, 402, 817, 810]	-1.34 (± 0.15)	-1.95 (± 0.14)	-1.91 (± 0.15)	-2.14 (± 0.15)
Week 8 [N=396, 385, 386, 386, 784, 769]	-1.85 (± 0.15)	-2.54 (± 0.15)	-2.43 (± 0.15)	-2.90 (± 0.15)
Week 12 [N=373, 369, 369, 379, 754, 750]	-2.05 (± 0.16)	-2.85 (± 0.16)	-2.70 (± 0.16)	-3.11 (± 0.16)
EoT [N=411, 409, 406, 413, 823, 816]	-2.06 (± 0.15)	-2.74 (± 0.15)	-2.63 (± 0.15)	-3.05 (± 0.15)

End point values	Solifenacin 5 mg +	Solifenacin 5 mg +		

	mirabegron 25 mg	mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: urgency episodes				
least squares mean (standard error)				
Week 4 [N=405, 406, 402, 402, 817, 810]	-2.42 (± 0.10)	-2.66 (± 0.10)		
Week 8 [N=396, 385, 386, 386, 784, 769]	-3.13 (± 0.11)	-3.28 (± 0.11)		
Week 12 [N=373, 369, 369, 379, 754, 750]	-3.45 (± 0.11)	-3.50 (± 0.11)		
EoT [N=411, 409, 406, 413, 823, 816]	-3.38 (± 0.11)	-3.51 (± 0.11)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.074
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.69
upper limit	0.03
Variability estimate	Standard error of the mean
Dispersion value	0.18

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.82
upper limit	-0.09
Variability estimate	Standard error of the mean
Dispersion value	0.18

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.01
upper limit	-0.28
Variability estimate	Standard error of the mean
Dispersion value	0.18

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.24
upper limit	0.51
Variability estimate	Standard error of the mean
Dispersion value	0.19

Secondary: Number of Nocturia Episodes at Weeks 4, 8, 12 and EoT

End point title	Number of Nocturia Episodes at Weeks 4, 8, 12 and EoT

End point description:

A nocturia episode was defined as waking at night 1 or more times to void (i.e., any voiding associated with sleep disturbance between the time the participant goes to bed with the intention to sleep until the time the participant gets up in the morning with the intention to stay awake). The number of nocturia episodes was the number of times a participant recorded a nocturia episode during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. Only participants with ≥ 1 nocturia episode at baseline were included in the analysis. N is the number of participants analyzed with data available at each time point. LOCF was used for EOT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: nocturia episodes				
least squares mean (standard error)				
Week 4 [N=359, 341, 349, 341, 705, 693]	9.62 (± 0.43)	8.46 (± 0.36)	9.11 (± 0.47)	9.22 (± 0.42)
Week 8 [N=349, 327, 336, 329, 676, 655]	8.99 (± 0.44)	8.07 (± 0.34)	8.61 (± 0.45)	8.37 (± 0.38)
Week 12 [N=336, 312, 321, 320, 652, 641]	8.91 (± 0.43)	7.99 (± 0.37)	8.34 (± 0.48)	8.17 (± 0.39)
EoT [N=363, 344, 353, 350, 708, 697]	8.83 (± 0.42)	7.79 (± 0.35)	8.14 (± 0.45)	8.12 (± 0.37)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: nocturia episodes				
least squares mean (standard error)				
Week 4 [N=359, 341, 349, 341, 705, 693]	8.40 (± 0.25)	8.09 (± 0.25)		
Week 8 [N=349, 327, 336, 329, 676, 655]	7.63 (± 0.25)	7.11 (± 0.24)		
Week 12 [N=336, 312, 321, 320, 652, 641]	7.26 (± 0.24)	6.67 (± 0.23)		
EoT [N=363, 344, 353, 350, 708, 697]	7.33 (± 0.24)	6.67 (± 0.22)		

Statistical analyses

Statistical analysis title	Rate ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, >=65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of nocturia episodes used divided by number of valid diary days) included as a covariate and postbaseline number of valid diary days as offset variable.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	0.96
Variability estimate	Standard error of the mean
Dispersion value	0.05

Statistical analysis title	Rate ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, >=65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of nocturia episodes used divided by number of valid diary days) included as a covariate and postbaseline number of valid diary days as offset variable.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.88
Variability estimate	Standard error of the mean
Dispersion value	0.05

Statistical analysis title	Rate ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, >=65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of nocturia episodes used divided by number of valid diary days) included as a covariate and postbaseline number of valid diary days as offset variable.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.049
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.05

Statistical analysis title	Rate ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, >=65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of nocturia episodes used divided by number of valid diary days) included as a covariate and postbaseline number of valid diary days as offset variable.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	0.94
Variability estimate	Standard error of the mean
Dispersion value	0.05

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Number of Nocturia Episodes

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Number of Nocturia Episodes

End point description:

The number of nocturia episodes was the number of times a participant recorded a nocturia episode during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with ≥ 1 nocturia episode at baseline were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: nocturia episodes				
least squares mean (standard error)				
Week 4 [N=359, 341, 349, 341, 705, 693]	-1.27 (± 0.27)	-2.25 (± 0.28)	-1.80 (± 0.27)	-1.79 (± 0.28)
Week 8 [N=349, 327, 336, 329, 676, 655]	-1.94 (± 0.27)	-2.70 (± 0.28)	-2.41 (± 0.28)	-2.60 (± 0.28)
Week 12 [N=336, 312, 321, 320, 652, 641]	-1.95 (± 0.29)	-2.77 (± 0.30)	-2.73 (± 0.29)	-2.89 (± 0.29)
EoT [N=363, 344, 353, 350, 708, 697]	-2.05 (± 0.27)	-2.91 (± 0.28)	-2.75 (± 0.28)	-2.81 (± 0.28)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: nocturia episodes				
least squares mean (standard error)				
Week 4 [N=359, 341, 349, 341, 705, 693]	-2.39 (± 0.19)	-2.50 (± 0.19)		
Week 8 [N=349, 327, 336, 329, 676, 655]	-3.13 (± 0.20)	-3.48 (± 0.20)		
Week 12 [N=336, 312, 321, 320, 652, 641]	-3.49 (± 0.21)	-3.96 (± 0.21)		
EoT [N=363, 344, 353, 350, 708, 697]	-3.42 (± 0.20)	-3.96 (± 0.20)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.28
upper limit	0.06
Variability estimate	Standard error of the mean
Dispersion value	0.34

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.83
upper limit	-0.48
Variability estimate	Standard error of the mean
Dispersion value	0.34

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.14
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.18
upper limit	0.17
Variability estimate	Standard error of the mean
Dispersion value	0.34

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.88
upper limit	-0.54
Variability estimate	Standard error of the mean
Dispersion value	0.34

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Mean Number of Nocturia Episodes per 24 Hours

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Mean Number of Nocturia Episodes per 24 Hours

End point description:

The mean number of nocturia episodes was calculated from data recorded by the participant per day on valid diary days during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with ≥ 1 nocturia episode at baseline were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: nocturia episodes				
least squares mean (standard error)				
Week 4 [N=359, 341, 349, 341, 705, 693]	-0.17 (± 0.04)	-0.31 (± 0.04)	-0.25 (± 0.04)	-0.24 (± 0.04)
Week 8 [N=349, 327, 336, 329, 676, 655]	-0.27 (± 0.04)	-0.37 (± 0.04)	-0.35 (± 0.04)	-0.36 (± 0.04)
Week 12 [N=336, 312, 321, 320, 652, 641]	-0.26 (± 0.04)	-0.38 (± 0.04)	-0.39 (± 0.04)	-0.41 (± 0.04)
EoT [N=363, 344, 353, 350, 708, 697]	-0.27 (± 0.04)	-0.40 (± 0.04)	-0.39 (± 0.04)	-0.39 (± 0.04)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: nocturia episodes				
least squares mean (standard error)				
Week 4 [N=359, 341, 349, 341, 705, 693]	-0.33 (± 0.03)	-0.35 (± 0.03)		
Week 8 [N=349, 327, 336, 329, 676, 655]	-0.44 (± 0.03)	-0.50 (± 0.03)		
Week 12 [N=336, 312, 321, 320, 652, 641]	-0.49 (± 0.03)	-0.56 (± 0.03)		
EoT [N=363, 344, 353, 350, 708, 697]	-0.48 (± 0.03)	-0.56 (± 0.03)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.065
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.01
Variability estimate	Standard error of the mean
Dispersion value	0.05

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	-0.07
Variability estimate	Standard error of the mean
Dispersion value	0.05

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.02
Variability estimate	Standard error of the mean
Dispersion value	0.05

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	-0.07
Variability estimate	Standard error of the mean
Dispersion value	0.05

Secondary: Number of Pads Used at Weeks 4, 8, 12 and EoT

End point title	Number of Pads Used at Weeks 4, 8, 12 and EoT

End point description:

The number of pads used was the number of times a participant recorded a new pad used during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. Only participants with ≥ 1 pad used at baseline were included in the analysis. N is the number of participants analyzed with data available at each time point. LOCF was used for EOT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: pads				
least squares mean (standard error)				
Week 4 [N=248, 250, 247, 257, 506, 499]	15.62 (± 1.33)	13.46 (± 1.24)	10.05 (± 1.21)	11.41 (± 1.23)
Week 8 [N=239, 237, 240, 243, 485, 472]	12.75 (± 1.22)	10.79 (± 1.05)	9.53 (± 1.39)	8.45 (± 1.03)
Week 12 [N=226, 225, 229, 241, 468, 461]	12.62 (± 1.21)	9.65 (± 1.00)	8.44 (± 1.26)	8.21 (± 0.95)
EoT [N=252, 252, 249, 262, 510, 502]	12.29 (± 1.11)	10.15 (± 0.97)	8.16 (± 1.17)	8.53 (± 0.94)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: pads				

least squares mean (standard error)				
Week 4 [N=248, 250, 247, 257, 506, 499]	9.71 (± 0.70)	9.34 (± 0.68)		
Week 8 [N=239, 237, 240, 243, 485, 472]	8.07 (± 0.65)	7.58 (± 0.62)		
Week 12 [N=226, 225, 229, 241, 468, 461]	6.60 (± 0.58)	6.64 (± 0.61)		
EoT [N=252, 252, 249, 262, 510, 502]	7.04 (± 0.56)	6.80 (± 0.59)		

Statistical analyses

Statistical analysis title	Rate ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, >=65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of pads used divided by number of valid diary days) included as a covariate and postbaseline number of valid diary days as offset variable.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.938
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.27
Variability estimate	Standard error of the mean
Dispersion value	0.12

Statistical analysis title	Rate ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, >=65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of pads used divided by number of valid diary days) included as a covariate and postbaseline number of valid diary days as offset variable.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.967
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.25
Variability estimate	Standard error of the mean
Dispersion value	0.12

Statistical analysis title	Rate ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, >=65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of pads used divided by number of valid diary days) included as a covariate and postbaseline number of valid diary days as offset variable.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.92
Variability estimate	Standard error of the mean
Dispersion value	0.12

Statistical analysis title	Rate ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Rate ratio of number of incontinence episodes during the 7-day diary between the given combination group and the given monotherapy group calculated from a negative binomial regression model incl. treatment group, sex, age group (<65, >=65 years), geographic region and previous OAB medication (yes, no) as factors, baseline log(number of pads used divided by number of valid diary days) included as a covariate and postbaseline number of valid diary days as offset variable.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.069
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.02
Variability estimate	Standard error of the mean
Dispersion value	0.12

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Number of Pads Used

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Number of Pads Used

End point description:

The number of pads used was the number of times a participant recorded a new pad used during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with ≥ 1 pad used at baseline were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: pads				
least squares mean (standard error)				
Week 4 [N=248, 250, 247, 257, 506, 499]	-3.69 (± 0.71)	-5.68 (± 0.71)	-7.83 (± 0.71)	-8.23 (± 0.70)
Week 8 [N=239, 237, 240, 243, 485, 472]	-6.24 (± 0.77)	-8.44 (± 0.77)	-8.43 (± 0.76)	-10.67 (± 0.76)
Week 12 [N=226, 225, 229, 241, 468, 461]	-6.29 (± 0.75)	-9.06 (± 0.75)	-9.41 (± 0.75)	-10.80 (± 0.73)
EoT [N=252, 252, 249, 262, 510, 502]	-6.60 (± 0.71)	-8.76 (± 0.71)	-9.80 (± 0.72)	-10.63 (± 0.70)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: pads				
least squares mean (standard error)				
Week 4 [N=248, 250, 247, 257, 506, 499]	-7.61 (± 0.50)	-8.58 (± 0.50)		
Week 8 [N=239, 237, 240, 243, 485, 472]	-9.49 (± 0.54)	-10.59 (± 0.54)		

Week 12 [N=226, 225, 229, 241, 468, 461] EoT [N=252, 252, 249, 262, 510, 502]	-10.66 (± 0.52) -10.67 (± 0.50)	-11.23 (± 0.53) -11.21 (± 0.50)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.958
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.73
upper limit	1.64
Variability estimate	Standard error of the mean
Dispersion value	0.86

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.27
upper limit	1.11

Variability estimate	Standard error of the mean
Dispersion value	0.86

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.028
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.62
upper limit	-0.2
Variability estimate	Standard error of the mean
Dispersion value	0.87

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.108
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.13
upper limit	0.31
Variability estimate	Standard error of the mean
Dispersion value	0.88

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Mean Number of Pads Used per 24 Hours

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Mean Number of Pads Used per 24 Hours

End point description:

The mean number of pads used was calculated from data recorded by the participant per day on valid diary days during the 7-day micturition diary period prior to each visit. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with ≥ 1 pads used at baseline were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: pads				
least squares mean (standard error)				
Week 4 [N=248, 250, 247, 257, 506, 499]	-0.52 (± 0.10)	-0.81 (± 0.10)	-1.12 (± 0.10)	-1.19 (± 0.10)
Week 8 [N=239, 237, 240, 243, 485, 472]	-0.82 (± 0.11)	-1.20 (± 0.11)	-1.24 (± 0.11)	-1.53 (± 0.11)
Week 12 [N=226, 225, 229, 241, 468, 461]	-0.92 (± 0.11)	-1.30 (± 0.11)	-1.37 (± 0.11)	-1.56 (± 0.11)
EoT [N=252, 252, 249, 262, 510, 502]	-0.94 (± 0.10)	-1.26 (± 0.10)	-1.41 (± 0.10)	-1.53 (± 0.10)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: pads				
least squares mean (standard error)				
Week 4 [N=248, 250, 247, 257, 506, 499]	-1.09 (± 0.07)	-1.23 (± 0.07)		
Week 8 [N=239, 237, 240, 243, 485, 472]	-1.36 (± 0.08)	-1.51 (± 0.08)		
Week 12 [N=226, 225, 229, 241, 468, 461]	-1.54 (± 0.08)	-1.59 (± 0.08)		
EoT [N=252, 252, 249, 262, 510, 502]	-1.53 (± 0.07)	-1.58 (± 0.07)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.993
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.25
Variability estimate	Standard error of the mean
Dispersion value	0.13

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.19
Variability estimate	Standard error of the mean
Dispersion value	0.13

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron

25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.035
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	-0.02
Variability estimate	Standard error of the mean
Dispersion value	0.13

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.169
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	0.08
Variability estimate	Standard error of the mean
Dispersion value	0.13

Secondary: Number of Incontinence-Free Days at Weeks 4, 8, 12 and EoT

End point title	Number of Incontinence-Free Days at Weeks 4, 8, 12 and EoT

End point description:

The number of incontinence-free days was the number of valid diary days during the 7-day micturition diary period with no incontinence episodes recorded. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EOT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: incontinence-free days				
arithmetic mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	2.25 (± 0.13)	2.48 (± 0.13)	2.98 (± 0.13)	2.74 (± 0.14)
Week 8 [N=397, 385, 386, 386, 784, 769]	2.92 (± 0.14)	3.17 (± 0.14)	3.63 (± 0.15)	3.31 (± 0.14)
Week 12 [N=374, 369, 369, 379, 754, 750]	3.19 (± 0.15)	3.69 (± 0.15)	3.96 (± 0.15)	3.68 (± 0.14)
EoT [N=412, 409, 406, 413, 823, 816]	3.16 (± 0.14)	3.51 (± 0.14)	3.89 (± 0.14)	3.61 (± 0.14)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: incontinence-free days				
arithmetic mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	3.08 (± 0.10)	3.37 (± 0.10)		
Week 8 [N=397, 385, 386, 386, 784, 769]	3.88 (± 0.10)	4.01 (± 0.10)		
Week 12 [N=374, 369, 369, 379, 754, 750]	4.33 (± 0.10)	4.25 (± 0.10)		
EoT [N=412, 409, 406, 413, 823, 816]	4.20 (± 0.10)	4.23 (± 0.10)		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline logarithm of mean number of incontinence episodes per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.37

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.68

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline logarithm of mean number of incontinence episodes per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.68

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline logarithm of mean number of incontinence episodes per 24 hours as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.29
upper limit	1.95

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:	
Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline logarithm of mean number of incontinence episodes per 24 hours as a covariate.	
Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.68

Secondary: Number of Days with < 8 Micturitions at Weeks 4, 8, 12 and EoT

End point title	Number of Days with < 8 Micturitions at Weeks 4, 8, 12 and EoT
End point description:	
The number of days with < 8 micturitions was the number of valid diary days during the 7-day micturition diary period with less than 8 micturitions per day. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EOT.	
End point type	Secondary
End point timeframe:	
Weeks 4, 8, 12 and EoT (up to 12 weeks)	

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: days				
arithmetic mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	1.49 (± 0.10)	1.74 (± 0.10)	1.55 (± 0.10)	1.86 (± 0.11)
Week 8 [N=397, 385, 386, 386, 784, 769]	1.69 (± 0.10)	2.08 (± 0.12)	1.99 (± 0.11)	2.22 (± 0.12)
Week 12 [N=374, 369, 369, 379, 754, 750]	1.76 (± 0.11)	2.31 (± 0.13)	2.25 (± 0.12)	2.49 (± 0.13)
EoT [N=412, 409, 406, 413, 823, 816]	1.80 (± 0.11)	2.28 (± 0.12)	2.22 (± 0.12)	2.49 (± 0.12)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: days				
arithmetic mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	2.07 (± 0.08)	2.11 (± 0.08)		
Week 8 [N=397, 385, 386, 386, 784, 769]	2.59 (± 0.09)	2.70 (± 0.09)		
Week 12 [N=374, 369, 369, 379, 754, 750]	2.87 (± 0.09)	2.95 (± 0.10)		
EoT [N=412, 409, 406, 413, 823, 816]	2.84 (± 0.09)	2.92 (± 0.09)		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.5

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.59

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.19
upper limit	1.77

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of micturitions per 24 hours as a covariate

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	1.84

Secondary: Number of Incontinence-Free Days with < 8 Micturitions per Day at

Weeks 4, 8, 12 and EoT

End point title	Number of Incontinence-Free Days with < 8 Micturitions per Day at Weeks 4, 8, 12 and EoT

End point description:

The number of incontinence-free days with < 8 micturitions per day was the number of valid diary days during the 7-day micturition diary period with no incontinence episodes recorded and with < 8 micturitions per day. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EOT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: days				
arithmetic mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	0.64 (± 0.07)	0.84 (± 0.08)	0.87 (± 0.08)	0.91 (± 0.08)
Week 8 [N=397, 385, 386, 386, 784, 769]	0.85 (± 0.08)	1.20 (± 0.10)	1.23 (± 0.10)	1.31 (± 0.10)
Week 12 [N=374, 369, 369, 379, 754, 750]	0.98 (± 0.09)	1.47 (± 0.11)	1.50 (± 0.11)	1.60 (± 0.11)
EoT [N=412, 409, 406, 413, 823, 816]	1.01 (± 0.08)	1.40 (± 0.10)	1.47 (± 0.10)	1.59 (± 0.10)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: days				
arithmetic mean (standard error)				
Week 4 [N=406, 406, 402, 402, 817, 810]	1.21 (± 0.07)	1.32 (± 0.07)		
Week 8 [N=397, 385, 386, 386, 784, 769]	1.75 (± 0.08)	1.89 (± 0.08)		
Week 12 [N=374, 369, 369, 379, 754, 750]	2.12 (± 0.09)	2.15 (± 0.09)		
EoT [N=412, 409, 406, 413, 823, 816]	2.04 (± 0.08)	2.12 (± 0.09)		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as

factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.64

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.14
upper limit	1.75

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.65

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.32
upper limit	2.06

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a overdispersed binomial regression model (Williams' method) including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of micturitions per 24 hours as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Overdispersed binomial regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.33
upper limit	2.07

Secondary: Change from Baseline in Patient Perception of Bladder Condition Questionnaire (PPBC) at Weeks 4, 8, 12 and EoT

End point title	Change from Baseline in Patient Perception of Bladder Condition Questionnaire (PPBC) at Weeks 4, 8, 12 and EoT

End point description:

The PPBC was a validated, global assessment tool using a 6-point Likert scale on which participants rated their subjective impression of their current bladder condition. Participants assessed their bladder condition using this scale: 1. Does not cause me any problems at all; 2. Causes me some very minor problems; 3. Causes me some minor problems; 4. Causes me (some) moderate problems; 5. Causes me severe problems; 6. Causes me many severe problems. The analysis population is FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 393, 394, 791, 791]	-0.54 (± 0.06)	-0.72 (± 0.06)	-0.83 (± 0.06)	-0.81 (± 0.06)
Week 8 [N=381, 372, 380, 385, 758, 761]]	-0.80 (± 0.06)	-1.07 (± 0.06)	-1.12 (± 0.06)	-1.18 (± 0.06)
Week 12 [N=371, 362, 366, 375, 739, 735]	-0.95 (± 0.06)	-1.23 (± 0.06)	-1.34 (± 0.06)	-1.32 (± 0.06)
EoT [N=400, 393, 398, 399, 801, 795]	-0.91 (± 0.06)	-1.18 (± 0.06)	-1.31 (± 0.06)	-1.27 (± 0.06)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 393, 394, 791, 791]	-0.99 (± 0.04)	-1.07 (± 0.04)		
Week 8 [N=381, 372, 380, 385, 758, 761]]	-1.32 (± 0.04)	-1.48 (± 0.04)		
Week 12 [N=371, 362, 366, 375, 739, 735]	-1.57 (± 0.04)	-1.72 (± 0.04)		
EoT [N=400, 393, 398, 399, 801, 795]	-1.53 (± 0.04)	-1.66 (± 0.04)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	-0.11

Variability estimate	Standard error of the mean
Dispersion value	0.07

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	-0.25
Variability estimate	Standard error of the mean
Dispersion value	0.07

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	-0.2
Variability estimate	Standard error of the mean
Dispersion value	0.07

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	-0.2
Variability estimate	Standard error of the mean
Dispersion value	0.07

Secondary: Change from Baseline to Weeks 4, 8 and 12 in the OAB-q Symptom Bother Score

End point title	Change from Baseline to Weeks 4, 8 and 12 in the OAB-q Symptom Bother Score

End point description:

The OAB-q was a self-reported questionnaire with items relating to symptom bother and health-related quality of life (HRQoL). The symptom bother portion (seen in this endpoint) consisted of 8 items, rated on a 6-point Likert scale (1 through 6). The total symptom bother score was calculated from the 8 answers and then transformed to range from 0 (least severity) to 100 (worst severity). A negative change from baseline indicated an improvement. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	-13.84 (± 0.92)	-17.05 (± 0.93)	-18.98 (± 0.93)	-19.53 (± 0.93)

Week 8 [N=381, 370, 380, 385, 757, 761]	-17.35 (± 0.98)	-22.79 (± 0.99)	-23.54 (± 0.98)	-24.69 (± 0.97)
Week 12 [N=371, 362, 366, 374, 738, 734]	-19.94 (± 1.01)	-24.44 (± 1.02)	-26.80 (± 1.02)	-26.72 (± 1.01)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	-23.46 (± 0.65)	-25.19 (± 0.65)		
Week 8 [N=381, 370, 380, 385, 757, 761]	-29.10 (± 0.69)	-30.04 (± 0.69)		
Week 12 [N=371, 362, 366, 374, 738, 734]	-31.70 (± 0.72)	-33.15 (± 0.72)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Health-Related Quality of Life Questionnaire (HRQL) Total Score

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Health-Related Quality of Life Questionnaire (HRQL) Total Score

End point description:

The OAB-q was a self-reported questionnaire with items relating to symptom bother and health-related quality of life (HRQoL). The HRQoL portion (seen in this endpoint) consisted of 25 HRQL items comprising 4 HRQL subscales (Coping, Concern, Sleep, and Social Interaction), scored 1 -6. The total score was calculated by adding the 4 HRQoL subscale scores and transforming to a scale from 0 to 100, with higher scores indicating better quality of life. A positive change from baseline indicated an improvement. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	10.16 (± 0.83)	13.54 (± 0.83)	15.28 (± 0.83)	14.78 (± 0.83)

Week 8 [N=381, 370, 380, 385, 757, 761]	14.51 (± 0.88)	17.95 (± 0.89)	18.54 (± 0.88)	18.57 (± 0.88)
Week 12 [N=371, 362, 366, 374, 738, 734]	15.76 (± 0.92)	19.59 (± 0.93)	21.48 (± 0.92)	20.54 (± 0.91)
EoT [N=400, 392, 398, 399, 800, 795]	15.37 (± 0.88)	18.94 (± 0.89)	21.00 (± 0.89)	20.15 (± 0.89)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	17.46 (± 0.58)	17.95 (± 0.59)		
Week 8 [N=381, 370, 380, 385, 757, 761]	22.30 (± 0.62)	22.45 (± 0.62)		
Week 12 [N=371, 362, 366, 374, 738, 734]	24.63 (± 0.65)	24.93 (± 0.65)		
EoT [N=400, 392, 398, 399, 800, 795]	23.96 (± 0.63)	24.30 (± 0.63)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	3.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.69
upper limit	5.94
Variability estimate	Standard error of the mean
Dispersion value	1.08

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	4.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.03
upper limit	6.29
Variability estimate	Standard error of the mean
Dispersion value	1.09

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	5.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.88
upper limit	7.15
Variability estimate	Standard error of the mean
Dispersion value	1.09

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.17
upper limit	5.43
Variability estimate	Standard error of the mean
Dispersion value	1.09

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in HRQL Subscale Score: Coping

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in HRQL Subscale Score: Coping

End point description:

The OAB-q was a self-reported questionnaire with items relating to symptom bother and health-related quality of life (HRQoL). The HRQoL portion consists of 25 HRQL items comprising 4 HRQL subscales (Coping, Concern, Sleep, and Social Interaction), scored 1-6. The Coping score was calculated by adding 8 response scores and transforming to a scale from 0 to 100, with higher scores indicating better quality of life. A positive change from baseline indicated an improvement. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	11.74 (± 0.99)	14.87 (± 1.00)	17.68 (± 1.00)	16.52 (± 1.00)
Week 8 [N=381, 370, 380, 385, 757, 761]	16.13 (± 1.04)	20.64 (± 1.05)	21.52 (± 1.04)	21.69 (± 1.03)
Week 12 [N=371, 362, 366, 374, 738, 734]	18.17 (± 1.09)	22.04 (± 1.10)	24.94 (± 1.10)	23.67 (± 1.09)
EoT [N=400, 392, 398, 399, 800, 795]	17.73 (± 1.05)	21.28 (± 1.06)	24.32 (± 1.05)	23.25 (± 1.05)

End point values	Solifenacin 5 mg +	Solifenacin 5 mg +		

	mirabegron 25 mg	mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	19.31 (± 0.70)	20.36 (± 0.70)		
Week 8 [N=381, 370, 380, 385, 757, 761]	25.49 (± 0.74)	25.85 (± 0.73)		
Week 12 [N=371, 362, 366, 374, 738, 734]	28.32 (± 0.77)	29.03 (± 0.78)		
EoT [N=400, 392, 398, 399, 800, 795]	27.37 (± 0.74)	28.12 (± 0.75)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	4.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	6.65
Variability estimate	Standard error of the mean
Dispersion value	1.29

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Lest squares mean difference
Point estimate	4.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.34
upper limit	7.4
Variability estimate	Standard error of the mean
Dispersion value	1.29

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	6.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.55
upper limit	8.63
Variability estimate	Standard error of the mean
Dispersion value	1.3

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.27
upper limit	6.33
Variability estimate	Standard error of the mean
Dispersion value	1.29

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in HRQL Subscale Score: Concern

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in HRQL Subscale Score: Concern

End point description:

The OAB-q was a self-reported questionnaire with items relating to symptom bother and health-related quality of life (HRQoL). The HRQoL portion consists of 25 HRQL items comprising 4 HRQL subscales (Coping, Concern, Sleep, and Social Interaction), scored 1-6. The Concern score was calculated by adding 7 response scores and transforming to a scale from 0 to 100, with higher scores indicating better quality of life. A positive change from baseline indicated an improvement. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	11.24 (± 0.95)	15.89 (± 0.96)	17.39 (± 0.95)	17.18 (± 0.95)
Week 8 [N=381, 370, 380, 385, 757, 761]	16.10 (± 0.99)	20.63 (± 1.01)	20.55 (± 1.00)	20.96 (± 0.99)
Week 12 [N=371, 362, 366, 374, 738, 734]	17.53 (± 1.03)	22.37 (± 1.04)	23.62 (± 1.04)	23.19 (± 1.03)
EoT [N=400, 392, 398, 399, 800, 795]	16.98 (± 1.00)	21.55 (± 1.01)	23.07 (± 1.00)	22.65 (± 1.00)

End point values	Solifenacin 5 mg + mirabegron 25	Solifenacin 5 mg + mirabegron 50		

	mg	mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	20.48 (± 0.67)	21.09 (± 0.67)		
Week 8 [N=381, 370, 380, 385, 757, 761]	25.26 (± 0.71)	25.65 (± 0.70)		
Week 12 [N=371, 362, 366, 374, 738, 734]	27.53 (± 0.73)	28.24 (± 0.73)		
EoT [N=400, 392, 398, 399, 800, 795]	26.89 (± 0.71)	27.47 (± 0.71)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	4.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.84
upper limit	6.63
Variability estimate	Standard error of the mean
Dispersion value	1.22

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	4.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.42
upper limit	7.22
Variability estimate	Standard error of the mean
Dispersion value	1.22

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	5.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.93
upper limit	7.75
Variability estimate	Standard error of the mean
Dispersion value	1.23

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	4.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.01
upper limit	6.81
Variability estimate	Standard error of the mean
Dispersion value	1.22

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in HRQL Subscale Score: Sleep

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in HRQL Subscale Score: Sleep

End point description:

The OAB-q was a self-reported questionnaire with items relating to symptom bother and health-related quality of life (HRQoL). The HRQoL portion consisted of 25 HRQL items comprising 4 HRQL subscales (Coping, Concern, Sleep, and Social Interaction), scored 1-6. The Sleep score was calculated by adding 5 response scores and transforming to a scale from 0 to 100, with higher scores indicating better quality of life. A positive change from baseline indicated an improvement. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	9.28 (± 0.95)	12.70 (± 0.96)	13.80 (± 0.96)	13.08 (± 0.96)
Week 8 [N=381, 370, 380, 385, 757, 761]	13.58 (± 1.03)	16.39 (± 1.05)	17.33 (± 1.03)	16.43 (± 1.03)
Week 12 [N=371, 362, 366, 374, 738, 734]	14.40 (± 1.05)	18.04 (± 1.06)	19.16 (± 1.06)	18.35 (± 1.05)
EoT [N=400, 392, 398, 399, 800, 795]	14.17 (± 1.01)	17.51 (± 1.02)	19.11 (± 1.02)	17.97 (± 1.01)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	15.97 (± 0.68)	16.66 (± 0.68)		
Week 8 [N=381, 370, 380, 385, 757, 761]	20.29 (± 0.73)	20.49 (± 0.73)		
Week 12 [N=371, 362, 366, 374, 738, 734]	22.97 (± 0.74)	22.76 (± 0.75)		
EoT [N=400, 392, 398, 399, 800, 795]	22.39 (± 0.72)	22.39 (± 0.72)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	4.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.98
upper limit	6.85
Variability estimate	Standard error of the mean
Dispersion value	1.24

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	4.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.98
upper limit	6.86
Variability estimate	Standard error of the mean
Dispersion value	1.24

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	4.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.42
upper limit	7.32
Variability estimate	Standard error of the mean
Dispersion value	1.25

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	3.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	5.72
Variability estimate	Standard error of the mean
Dispersion value	1.24

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in HRQL Subscale Score: Social

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in HRQL Subscale Score: Social

End point description:

The OAB-q was a self-reported questionnaire with items relating to symptom bother and health-related quality of life (HRQoL). The HRQoL portion consisted of 25 HRQL items comprising 4 HRQL subscales (Coping, Concern, Sleep, and Social Interaction), scored 1-6. The Social score was calculated by adding 5 response scores and transforming to a scale from 0 to 100, with higher scores indicating better quality of life. A positive change from baseline indicated an improvement. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	7.07 (± 0.78)	9.04 (± 0.79)	10.19 (± 0.78)	9.89 (± 0.78)
Week 8 [N=381, 370, 380, 385, 757, 761]	10.65 (± 0.82)	11.50 (± 0.83)	12.34 (± 0.82)	12.02 (± 0.81)
Week 12 [N=371, 362, 366, 374, 738, 734]	10.84 (± 0.83)	13.43 (± 0.84)	15.35 (± 0.84)	13.74 (± 0.83)
EoT [N=400, 392, 398, 399, 800, 795]	10.56 (± 0.81)	13.04 (± 0.81)	14.87 (± 0.81)	13.57 (± 0.81)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=397, 388, 392, 394, 790, 789]	11.55 (± 0.55)	11.25 (± 0.55)		
Week 8 [N=381, 370, 380, 385, 757, 761]	14.89 (± 0.58)	14.73 (± 0.58)		
Week 12 [N=371, 362, 366, 374, 738, 734]	16.16 (± 0.59)	16.08 (± 0.59)		
EoT [N=400, 392, 398, 399, 800, 795]	15.84 (± 0.57)	15.82 (± 0.57)		

Statistical analyses

Statistical analysis title	Difference vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.022
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	2.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	4.21
Variability estimate	Standard error of the mean
Dispersion value	0.99

Statistical analysis title	Difference vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (solifenacin 5 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	2.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	4.19
Variability estimate	Standard error of the mean
Dispersion value	0.99

Statistical analysis title	Difference vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 25 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 25 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	4.74
Variability estimate	Standard error of the mean
Dispersion value	0.99

Statistical analysis title	Difference vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Difference of the adjusted mean calculated by subtracting the adjusted mean of the monotherapy group (mirabegron 50 mg) from the adjusted mean of the combination group (solifenacin 5 mg + mirabegron 50 mg) based on the ANCOVA model with treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as fixed factors and baseline value as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.337
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.99
upper limit	2.89
Variability estimate	Standard error of the mean
Dispersion value	0.99

Secondary: Patient's Global Impression of Change (PGIC) Scale: Impression in Bladder Symptoms at Week 12 and EoT

End point title	Patient's Global Impression of Change (PGIC) Scale: Impression in Bladder Symptoms at Week 12 and EoT

End point description:

The PGIC was a 2-part questionnaire, assessing both the change in the participant's overall condition and change in bladder condition since the start of the study (from very much worse to very much improved). The analysis population was the FAS. The number of participants analyzed includes participants with data available. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Week 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 12: Very much improved	8.4	13.9	15.1	13.5
Week 12: Much improved	29.7	32.9	34.8	40.5
Week 12: Minimally improved	29.7	26.8	26.5	25.8
Week 12: No change	17.5	12.9	9.7	8.9
Week 12: Minimally worse	4.1	1.5	2.2	1.7
Week 12: Much worse	1.0	1.0	1.2	0.5
Week 12: Very much worse	0.5	0.5	0.7	0.5
EoT: Very much improved	8.4	13.9	15.1	13.5
EoT: Much improved	30.4	33.2	34.8	41.0
EoT: Minimally improved	29.9	26.8	27.0	26.3
EoT: No change	18.2	13.4	10.2	9.6
EoT: Minimally worse	4.1	1.5	2.2	1.7
EoT: Much worse	1.0	1.0	1.2	0.7
EoT: Very much worse	0.5	0.5	0.7	0.5

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 12: Very much improved	19.8	27.1		
Week 12: Much improved	39.8	34.0		
Week 12: Minimally improved	22.2	20.7		
Week 12: No change	7.7	7.3		
Week 12: Minimally worse	0.8	0.8		
Week 12: Much worse	0.2	0		
Week 12: Very much worse	0.2	0.5		
EoT: Very much improved	20.0	27.1		
EoT: Much improved	40.0	34.6		
EoT: Minimally improved	22.6	21.3		
EoT: No change	7.9	7.4		
EoT: Minimally worse	0.8	0.8		
EoT: Much worse	0.4	0		
EoT: Very much worse	0.2	0.6		

Statistical analyses

No statistical analyses for this end point

Secondary: PGIC Scale: Impression in General Health at Week 12 and EoT

End point title	PGIC Scale: Impression in General Health at Week 12 and EoT

End point description:

The PGIC was a 2-part questionnaire, assessing both the change in the participant's overall condition and change in bladder condition since the start of the study (from very much worse to very much improved). The analysis population was the FAS. The number of participants analyzed includes participants with data available. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Week 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 12: Very much improved	4.8	8.0	7.3	7.7

Week 12: Much improved	23.9	28.0	29.2	31.8
Week 12: Minimally improved	23.9	21.5	22.4	24.1
Week 12: No change	31.8	27.8	27.5	25.3
Week 12: Minimally worse	4.3	2.9	2.2	1.4
Week 12: Much worse	1.7	0.7	1.2	0.5
Week 12: Very much worse	0.2	0.5	0.5	0.5
EoT: Very much improved	4.8	8.0	7.3	7.7
EoT: Much improved	24.2	28.0	29.2	31.8
EoT: Minimally improved	24.4	21.5	22.9	24.1
EoT: No change	32.3	28.3	27.7	26.5
EoT: Minimally worse	4.3	2.9	2.4	1.9
EoT: Much worse	1.9	0.7	1.2	0.5
EoT: Very much worse	0.5	0.7	0.5	0.7

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 12: Very much improved	10.3	14.6		
Week 12: Much improved	33.4	30.2		
Week 12: Minimally improved	20.1	20.9		
Week 12: No change	23.9	21.6		
Week 12: Minimally worse	2.5	2.2		
Week 12: Much worse	0.5	0.1		
Week 12: Very much worse	0.2	0.6		
EoT: Very much improved	10.3	14.6		
EoT: Much improved	33.6	30.4		
EoT: Minimally improved	20.2	21.3		
EoT: No change	24.3	21.9		
EoT: Minimally worse	2.8	2.7		
EoT: Much worse	0.5	0.2		
EoT: Very much worse	0.2	0.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to EoT in European Quality of Life in 5 Dimensions (EQ-5D) Questionnaire Subscale Score: Mobility

End point title	Change from Baseline to EoT in European Quality of Life in 5 Dimensions (EQ-5D) Questionnaire Subscale Score: Mobility

End point description:

The EQ-5D questionnaire was an international, standardized, nondisease specific instrument for describing and valuing health status, and had 5 dimensions: Mobility, Self-care, Usual Activities,

Pain/Discomfort, and Anxiety/Depression. Each dimension had 5 response levels ranging from level 1 (no problem or none) to level 5 (unable to perform activity). The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary
End point timeframe:	
Baseline and EoT (up to 12 weeks)	

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: participants				
number (not applicable)				
No problems -> no problems	204	239	225	227
No problems -> slight problems	16	20	25	22
No problems -> moderate problems	11	12	9	8
No problems -> severe problems	1	3	3	1
No problems -> unable to walk about	0	1	0	0
No problems -> no data	2	4	5	4
Slight problems -> no problems	33	35	35	30
Slight problems -> slight problems	27	20	24	19
Slight problems -> moderate problems	11	6	4	6
Slight problems -> severe problems	5	0	3	1
Slight problems -> unable to walk about	0	0	0	0
Slight problems -> no data	2	3	0	0
Moderate problems -> no problems	17	7	25	18
Moderate problems -> slight problems	18	10	10	22
Moderate problems -> moderate problems	21	12	10	13
Moderate problems -> severe problems	10	5	4	2
Moderate problems -> unable to walk about	0	0	0	1
Moderate problems -> no data	1	1	0	1
Severe problems -> no problems	3	5	9	7
Severe problems -> slight problems	6	7	3	4
Severe problems -> moderate problems	5	4	8	8
Severe problems -> severe problems	8	5	1	8
Severe problems -> unable to walk about	0	0	0	0
Severe problems -> no data	0	0	2	1
Unable to walk about -> no problems	0	0	0	2
Unable to walk about -> slight problems	1	0	0	0
Unable to walk about -> moderate problems	1	0	0	0
Unable to walk about -> severe problems	1	0	0	0
Unable to walk about -> unable to walk about	0	0	0	0
Unable to walk about -> no data	0	0	0	0
No data -> no problems	12	7	3	6
No data -> slight problems	1	0	1	2
No data -> moderate problems	0	3	1	0

No data -> severe problems	0	1	0	2
No data -> unable to walk about	0	0	0	0
No data -> no data	1	0	1	0

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: participants				
number (not applicable)				
No problems -> no problems	449	452		
No problems -> slight problems	41	38		
No problems -> moderate problems	20	10		
No problems -> severe problems	1	2		
No problems -> unable to walk about	0	1		
No problems -> no data	6	9		
Slight problems -> no problems	76	60		
Slight problems -> slight problems	40	49		
Slight problems -> moderate problems	19	9		
Slight problems -> severe problems	2	2		
Slight problems -> unable to walk about	0	0		
Slight problems -> no data	0	2		
Moderate problems -> no problems	31	46		
Moderate problems -> slight problems	24	25		
Moderate problems -> moderate problems	33	35		
Moderate problems -> severe problems	8	10		
Moderate problems -> unable to walk about	1	1		
Moderate problems -> no data	0	2		
Severe problems -> no problems	12	17		
Severe problems -> slight problems	13	8		
Severe problems -> moderate problems	15	15		
Severe problems -> severe problems	11	13		
Severe problems -> unable to walk about	0	0		
Severe problems -> no data	1	0		
Unable to walk about -> no problems	2	0		
Unable to walk about -> slight problems	0	0		
Unable to walk about -> moderate problems	0	1		
Unable to walk about -> severe problems	0	0		
Unable to walk about -> unable to walk about	0	0		
Unable to walk about -> no data	0	0		
No data -> no problems	15	16		
No data -> slight problems	4	2		
No data -> moderate problems	0	2		
No data -> severe problems	2	0		

No data -> unable to walk about	0	0		
No data -> no data	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to EoT in EQ-5D Questionnaire Subscale Score: Self-care

End point title	Change from Baseline to EoT in EQ-5D Questionnaire Subscale Score: Self-care

End point description:

The EQ-5D questionnaire was an international, standardized, nondisease specific instrument for describing and valuing health status, and had 5 dimensions: Mobility, Self-care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each dimension had 5 response levels ranging from level 1 (no problem or none) to level 5 (unable to perform activity). The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: participants				
number (not applicable)				
No problems -> no problems	311	324	336	319
No problems -> slight problems	21	17	9	20
No problems -> moderate problems	9	5	6	3
No problems -> severe problems	0	0	1	1
No problems -> unable to wash/dress myself	1	0	1	0
No problems -> no data	4	8	6	5
Slight problems -> no problems	17	13	16	25
Slight problems -> slight problems	10	10	12	12
Slight problems -> moderate problems	2	4	1	2
Slight problems -> severe problems	2	0	0	0
Slight problems -> unable to wash/dress myself	0	0	0	0
Slight problems -> no data	1	0	0	1
Moderate problems -> no problems	6	8	3	2
Moderate problems -> slight problems	3	1	8	3
Moderate problems -> moderate problems	9	1	2	6
Moderate problems -> severe problems	0	0	0	0
Moderate problems -> unable to wash/dress myself	0	0	0	0
Moderate problems -> no data	0	0	0	0

Severe problems -> no problems	2	2	2	1
Severe problems -> slight problems	1	0	0	3
Severe problems -> moderate problems	1	2	0	0
Severe problems -> severe problems	3	3	0	1
Severe problems -> unable to wash/dress myself	0	0	0	0
Severe problems -> no data	0	0	1	0
Unable to wash/dress myself -> no problems	0	1	1	0
Unable to wash/dress myself -> slight problems	0	0	0	0
Unable to wash/dress myself -> moderate problems	1	0	0	0
Unable to wash/dress myself -> severe problems	0	0	0	0
Unable to wash/dress myself ->unable to wash/dress	0	0	0	1
Unable to wash/dress myself -> no data	0	0	0	0
No data -> no problems	13	8	3	8
No data -> slight problems	0	2	2	1
No data -> moderate problems	0	1	0	1
No data -> severe problems	0	0	0	0
No data -> unable to wash/dress myself	0	0	0	0
No data -> no data	1	0	1	0

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: participants				
number (not applicable)				
No problems -> no problems	652	647		
No problems -> slight problems	22	26		
No problems -> moderate problems	12	4		
No problems -> severe problems	1	1		
No problems -> unable to wash/dress myself	0	0		
No problems -> no data	6	12		
Slight problems -> no problems	35	33		
Slight problems -> slight problems	22	26		
Slight problems -> moderate problems	3	7		
Slight problems -> severe problems	1	2		
Slight problems -> unable to wash/dress myself	0	0		
Slight problems -> no data	1	0		
Moderate problems -> no problems	17	16		
Moderate problems -> slight problems	9	7		
Moderate problems -> moderate problems	8	9		
Moderate problems -> severe problems	2	1		

Moderate problems -> unable to wash/dress myself	0	0		
Moderate problems -> no data	0	1		
Severe problems -> no problems	3	4		
Severe problems -> slight problems	3	3		
Severe problems -> moderate problems	7	3		
Severe problems -> severe problems	1	0		
Severe problems -> unable to wash/dress myself	0	0		
Severe problems -> no data	0	0		
Unable to wash/dress myself -> no problems	0	3		
Unable to wash/dress myself -> slight problems	0	0		
Unable to wash/dress myself -> moderate problems	0	0		
Unable to wash/dress myself -> severe problems	0	0		
Unable to wash/dress myself ->unable to wash/dress	0	0		
Unable to wash/dress myself -> no data	0	0		
No data -> no problems	20	18		
No data -> slight problems	1	0		
No data -> moderate problems	0	2		
No data -> severe problems	0	0		
No data -> unable to wash/dress myself	0	0		
No data -> no data	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to EoT in EQ-5D Questionnaire Subscale Score: Usual Activities

End point title	Change from Baseline to EoT in EQ-5D Questionnaire Subscale Score: Usual Activities

End point description:

The EQ-5D questionnaire was an international, standardized, nondisease specific instrument for describing and valuing health status, and had 5 dimensions: Mobility, Self-care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each dimension had 5 response levels ranging from level 1 (no problem or none) to level 5 (unable to perform activity). The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: participants				
number (not applicable)				
No problems -> No problems	196	228	219	223
No problems -> Slight problems	37	25	28	25
No problems -> Moderate problems	9	5	9	8
No problems -> Severe problems	2	0	1	0
No problems -> unable to do usual activities	0	0	0	0
No problems -> no data	2	5	4	3
Slight problems -> no problems	45	41	52	52
Slight problems -> slight problems	28	29	23	25
Slight problems -> moderate problems	15	9	3	8
Slight problems -> severe problems	2	0	2	0
Slight problems ->unable to do usual activities	0	0	0	0
Slight problems -> no data	2	2	0	3
Moderate problems -> no problems	14	13	15	13
Moderate problems -> slight problems	12	9	16	14
Moderate problems -> moderate problems	15	11	9	12
Moderate problems -> severe problems	1	3	0	1
Moderate problems ->unable to do usual activities	0	0	0	0
Moderate problems -> no data	1	1	2	0
Severe problems -> no problems	7	3	7	6
Severe problems -> slight problems	3	4	6	2
Severe problems -> moderate problems	6	7	5	6
Severe problems -> severe problems	4	1	1	3
Severe problems -> unable to do usual activities	0	1	0	0
Severe problems -> no data	0	0	1	0
Unable to do usual activities -> no problems	0	1	0	0
Unable to do usual activities -> slight problems	1	0	0	0
Unable to do usual activities -> moderate problems	2	1	1	0
Unable to do usual activities -> severe problems	0	0	1	0
Unable to do usual activities -> unable to do usu.	0	0	0	1
Unable to do usual activities -> no data	0	0	0	0
No data -> no problems	12	7	2	7
No data -> slight problems	1	2	3	1
No data -> moderate problems	0	2	0	2
No data -> severe problems	0	0	0	0
No data -> unable to do usual activities	0	0	0	0
No data -> no data	1	0	1	0

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: participants				
number (not applicable)				
No problems -> No problems	434	451		
No problems -> Slight problems	37	48		
No problems -> Moderate problems	13	11		
No problems -> Severe problems	1	1		
No problems -> unable to do usual activities	1	1		
No problems -> no data	5	8		
Slight problems -> no problems	98	95		
Slight problems -> slight problems	64	56		
Slight problems -> moderate problems	18	12		
Slight problems -> severe problems	2	3		
Slight problems ->unable to do usual activities	0	0		
Slight problems -> no data	2	4		
Moderate problems -> no problems	44	26		
Moderate problems -> slight problems	29	30		
Moderate problems -> moderate problems	25	17		
Moderate problems -> severe problems	3	3		
Moderate problems ->unable to do usual activities	0	1		
Moderate problems -> no data	0	1		
Severe problems -> no problems	7	11		
Severe problems -> slight problems	8	8		
Severe problems -> moderate problems	9	7		
Severe problems -> severe problems	2	9		
Severe problems -> unable to do usual activities	0	0		
Severe problems -> no data	0	0		
Unable to do usual activities -> no problems	0	2		
Unable to do usual activities -> slight problems	1	1		
Unable to do usual activities -> moderate problems	1	1		
Unable to do usual activities -> severe problems	0	0		
Unable to do usual activities -> unable to do usu.	1	0		
Unable to do usual activities -> no data	0	0		
No data -> no problems	18	15		
No data -> slight problems	1	3		
No data -> moderate problems	2	2		
No data -> severe problems	0	0		
No data -> unable to do usual activities	0	0		
No data -> no data	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to EoT in EQ-5D Questionnaire Subscale Score: Pain/Discomfort

End point title	Change from Baseline to EoT in EQ-5D Questionnaire Subscale Score: Pain/Discomfort

End point description:

The EQ-5D questionnaire was an international, standardized, nondisease specific instrument for describing and valuing health status, and had 5 dimensions: Mobility, Self-care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each dimension had 5 response levels ranging from level 1 (no problem or none) to level 5 (unable to perform activity). The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: participants				
number (not applicable)				
No pain/discomfort -> no pain/discomfort	131	175	153	154
No pain/discomfort -> slight pain/discomfort	38	29	37	33
No pain/discomfort -> moderate pain/discomfort	10	9	17	13
No pain/discomfort -> severe pain/discomfort	0	0	3	3
No pain/discomfort -> extreme pain/discomfort	0	0	0	0
No pain/discomfort -> no data	2	3	4	2
Slight pain/discomfort -> no pain/discomfort	53	51	44	46
Slight pain/discomfort -> slight pain/discomfort	54	49	45	47
Slight pain/discomfort -> moderate pain/discomfort	12	11	14	18
Slight pain/discomfort -> severe pain/discomfort	3	0	2	0
Slight pain/discomfort -> extreme pain/discomfort	2	0	1	0
Slight pain/discomfort -> no data	2	5	2	2
Moderate pain/discomfort -> no pain/discomfort	20	14	24	23

Moderate pain/discomfort -> slight pain/discomfort	23	15	20	22
Moderate pain/discomfort -> moderate pain/discomf	31	13	16	15
Moderate pain/discomfort -> severe pain/discomfort	4	5	3	1
Moderate pain/discomfort -> extreme pain/discomf	0	0	0	0
Moderate pain/discomfort -> no data	1	0	0	1
Severe pain/discomfort -> no pain/discomfort	2	4	3	1
Severe pain/discomfort -> slight pain/discomfort	3	4	6	4
Severe pain/discomfort -> moderate pain/discomfort	8	4	6	11
Severe pain/discomfort -> severe pain/discomfort	4	3	1	4
Severe pain/discomfort -> extreme pain/discomfort	0	1	1	0
Severe pain/discomfort -> no data	0	0	1	0
Extreme pain/discomfort -> no pain/discomfort	0	0	0	0
Extreme pain/discomfort -> slight pain/discomfort	1	0	0	2
Extreme pain/discomfort -> moderate pain/discomf	0	2	1	0
Extreme pain/discomfort -> severe pain/discomfort	0	2	1	2
Extreme pain/discomfort -> extreme pain/discomfort	0	0	0	0
Extreme pain/discomfort -> no data	0	0	0	1
No data -> no pain/discomfort	11	5	3	6
No data -> slight pain/discomfort	2	2	2	2
No data -> moderate pain/discomfort	0	4	0	2
No data -> severe pain/discomfort	0	0	0	0
No data -> extreme pain/discomfort	0	0	0	0
No data -> no data	1	0	1	0

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: participants				
number (not applicable)				
No pain/discomfort -> no pain/discomfort	290	317		
No pain/discomfort -> slight pain/discomfort	74	51		
No pain/discomfort -> moderate pain/discomfort	19	20		
No pain/discomfort -> severe pain/discomfort	3	1		
No pain/discomfort -> extreme pain/discomfort	1	0		

No pain/discomfort -> no data	3	8		
Slight pain/discomfort -> no pain/discomfort	117	105		
Slight pain/discomfort -> slight pain/discomfort	94	101		
Slight pain/discomfort -> moderate pain/discomfort	15	19		
Slight pain/discomfort -> severe pain/discomfort	6	3		
Slight pain/discomfort -> extreme pain/discomfort	0	0		
Slight pain/discomfort -> no data	2	4		
Moderate pain/discomfort -> no pain/discomfort	45	46		
Moderate pain/discomfort -> slight pain/discomfort	46	45		
Moderate pain/discomfort -> moderate pain/discomf	34	40		
Moderate pain/discomfort -> severe pain/discomfort	4	6		
Moderate pain/discomfort -> extreme pain/discomf	1	0		
Moderate pain/discomfort -> no data	1	1		
Severe pain/discomfort -> no pain/discomfort	8	12		
Severe pain/discomfort -> slight pain/discomfort	11	7		
Severe pain/discomfort -> moderate pain/discomfort	15	11		
Severe pain/discomfort -> severe pain/discomfort	7	8		
Severe pain/discomfort -> extreme pain/discomfort	1	0		
Severe pain/discomfort -> no data	1	0		
Extreme pain/discomfort -> no pain/discomfort	1	0		
Extreme pain/discomfort -> slight pain/discomfort	1	1		
Extreme pain/discomfort -> moderate pain/discomf	1	1		
Extreme pain/discomfort -> severe pain/discomfort	3	0		
Extreme pain/discomfort -> extreme pain/discomfort	1	0		
Extreme pain/discomfort -> no data	0	0		
No data -> no pain/discomfort	14	14		
No data -> slight pain/discomfort	6	3		
No data -> moderate pain/discomfort	1	3		
No data -> severe pain/discomfort	0	0		
No data -> extreme pain/discomfort	0	0		
No data -> no data	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to EoT in EQ-5D Questionnaire Subscale Score: Anxiety/Depression

End point title	Change from Baseline to EoT in EQ-5D Questionnaire Subscale Score: Anxiety/Depression

End point description:

The EQ-5D questionnaire was an international, standardized, nondisease specific instrument for describing and valuing health status, and had 5 dimensions: Mobility, Self-care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each dimension had 5 response levels ranging from level 1 (no problem or none) to level 5 (unable to perform activity). The analysis population was the FAS. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: participants				
number (not applicable)				
Not anxious -> not anxious	157	176	187	166
Not anxious -> slightly anxious	42	27	25	29
Not anxious -> moderately anxious	7	6	6	8
Not anxious -> severely anxious	0	2	5	1
Not anxious -> extremely anxious	0	0	1	0
Not anxious -> no data	2	3	2	1
Slightly anxious -> not anxious	42	60	54	59
Slightly anxious -> slightly anxious	49	40	45	40
Slightly anxious -> moderately anxious	17	16	12	17
Slightly anxious -> severely anxious	4	2	2	2
Slightly anxious -> extremely anxious	0	0	0	0
Slightly anxious -> no data	2	3	2	5
Moderately anxious -> not anxious	12	13	12	22
Moderately anxious -> slightly anxious	19	17	19	14
Moderately anxious -> moderately anxious	17	7	11	10
Moderately anxious -> severely anxious	2	3	0	1
Moderately anxious -> extremely anxious	0	1	0	0
Moderately anxious -> no data	1	1	2	0
Severely anxious -> not anxious	7	5	6	6
Severely anxious -> slightly anxious	3	3	4	5
Severely anxious -> moderately anxious	5	7	2	6
Severely anxious -> severely anxious	10	1	2	5
Severely anxious -> extremely anxious	1	0	0	1
Severely anxious -> no data	0	1	1	0
Extremely anxious -> not anxious	2	1	0	0
Extremely anxious -> slightly anxious	2	2	1	2
Extremely anxious -> moderately anxious	1	1	1	1
Extremely anxious -> severely anxious	0	1	1	3

Extremely anxious -> extremely anxious	0	0	2	1
Extremely anxious -> no data	0	0	0	0
No data -> not anxious	9	8	3	6
No data -> slightly anxious	4	1	2	2
No data -> moderately anxious	0	2	0	2
No data -> severely anxious	0	0	0	0
No data -> extremely anxious	0	0	0	0
No data -> no data	1	0	1	0

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: participants				
number (not applicable)				
Not anxious -> not anxious	360	370		
Not anxious -> slightly anxious	45	50		
Not anxious -> moderately anxious	13	11		
Not anxious -> severely anxious	2	1		
Not anxious -> extremely anxious	0	1		
Not anxious -> no data	3	6		
Slightly anxious -> not anxious	122	134		
Slightly anxious -> slightly anxious	79	65		
Slightly anxious -> moderately anxious	18	16		
Slightly anxious -> severely anxious	5	5		
Slightly anxious -> extremely anxious	1	0		
Slightly anxious -> no data	3	4		
Moderately anxious -> not anxious	42	35		
Moderately anxious -> slightly anxious	43	41		
Moderately anxious -> moderately anxious	18	23		
Moderately anxious -> severely anxious	8	7		
Moderately anxious -> extremely anxious	1	1		
Moderately anxious -> no data	1	3		
Severely anxious -> not anxious	12	8		
Severely anxious -> slightly anxious	11	6		
Severely anxious -> moderately anxious	6	7		
Severely anxious -> severely anxious	5	2		
Severely anxious -> extremely anxious	0	3		
Severely anxious -> no data	0	0		
Extremely anxious -> not anxious	2	1		
Extremely anxious -> slightly anxious	2	3		
Extremely anxious -> moderately anxious	2	1		
Extremely anxious -> severely anxious	0	1		
Extremely anxious -> extremely anxious	1	2		
Extremely anxious -> no data	0	0		
No data -> not anxious	13	14		

No data -> slightly anxious	6	3		
No data -> moderately anxious	1	2		
No data -> severely anxious	0	1		
No data -> extremely anxious	1	0		
No data -> no data	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 12 and EoT in Work Productivity and Activity Impairment: Specific Health Problem Questionnaire (WPAI:SHP) Score: Percent Time Work Missed

End point title	Change from Baseline to Week 12 and EoT in Work Productivity and Activity Impairment: Specific Health Problem Questionnaire (WPAI:SHP) Score: Percent Time Work Missed

End point description:

The WPAI:SHP was a self-administered questionnaire with 6 questions (Q1=Employment status; Q2=Hours absent from work due to the bladder condition; Q3=Hours absent from work due to other reasons; Q4=Hours actually worked; Q5=Impact of the bladder condition on productivity while working; Q6=Impact of the bladder condition on productivity while doing regular daily activities other than work) and a 1-week recall period. WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity, i.e., worse outcomes. A negative change from baseline indicated improvement. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with both baseline and post-baseline values are included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Week 12 [N=128, 127, 139, 130, 274, 244]	-2.98 (± 21.70)	-0.33 (± 22.03)	-1.72 (± 18.70)	-2.47 (± 14.13)
EoT [N=129, 127, 140, 132, 277, 247]	-2.96 (± 21.61)	-0.33 (± 22.03)	-1.71 (± 18.64)	-2.44 (± 14.03)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of work time missed				
arithmetic mean (standard deviation)				

Week 12 [N=128, 127, 139, 130, 274, 244]	-2.06 (± 20.93)	-2.59 (± 19.65)		
EoT [N=129, 127, 140, 132, 277, 247]	-1.48 (± 21.95)	-2.55 (± 19.54)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 12 and EoT in WPAI:SHP Score: Percent Impairment While Working

End point title	Change from Baseline to Week 12 and EoT in WPAI:SHP Score: Percent Impairment While Working

End point description:

The WPAI:SHP was a self-administered questionnaire with 6 questions (Q1=Employment status; Q2=Hours absent from work due to the bladder condition; Q3=Hours absent from work due to other reasons; Q4=Hours actually worked; Q5=Impact of the bladder condition on productivity while working; Q6=Impact of the bladder condition on productivity while doing regular daily activities other than work) and a 1-week recall period. WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity, i.e., worse outcomes. A negative change from baseline indicated improvement. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with both baseline and post-baseline values are included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Week 12 [N=126,122, 138, 130, 271, 241]	-11.27 (± 25.36)	-14.96 (± 26.21)	-12.25 (± 25.06)	-10.85 (± 25.58)
EoT [N=127, 122, 139, 132, 273, 244]	-11.18 (± 25.28)	-14.96 (± 26.21)	-12.37 (± 25.01)	-10.98 (± 25.68)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Week 12 [N=126,122, 138, 130, 271, 241]	-14.69 (± 26.99)	-13.07 (± 27.35)		

EoT [N=127, 122, 139, 132, 273, 244]	-14.58 (± 26.92)	-12.87 (± 27.31)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 12 and EoT in WPAI:SHP Score: Percent Overall Work Impairment

End point title	Change from Baseline to Week 12 and EoT in WPAI:SHP Score: Percent Overall Work Impairment

End point description:

The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with both baseline and post-baseline values are included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and week 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of overall work impairment				
arithmetic mean (standard deviation)				
Week 12 [N=126, 122, 138, 130, 271, 241]	-12.23 (± 25.66)	-15.70 (± 26.54)	-12.92 (± 26.71)	-12.31 (± 26.91)
EOT [N=127, 122, 139, 132, 273, 244]	-12.14 (± 25.58)	-15.70 (± 26.54)	-13.05 (± 26.65)	-12.42 (± 26.98)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of overall work impairment				
arithmetic mean (standard deviation)				
Week 12 [N=126, 122, 138, 130, 271, 241]	-16.31 (± 29.06)	-13.97 (± 29.30)		
EOT [N=127, 122, 139, 132, 273, 244]	-16.07 (± 29.12)	-13.76 (± 29.25)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 12 and EoT in WPAI:SHP Score: Percent Activity Impairment

End point title	Change from Baseline to Week 12 and EoT in WPAI:SHP Score: Percent Activity Impairment

End point description:

The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Only participants with both baseline and post-baseline values are included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and week 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Week 12 [N=368, 358, 365, 373, 730, 731]	-11.49 (± 27.31)	-16.89 (± 27.57)	-14.99 (± 27.81)	-16.19 (± 29.16)
EoT [N=375, 361, 368, 380, 736, 743]	-11.55 (± 27.19)	-16.72 (± 27.82)	-15.05 (± 27.95)	-16.05 (± 28.95)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Week 12 [N=368, 358, 365, 373, 730, 731]	-19.60 (± 28.80)	-18.92 (± 29.47)		
EoT [N=375, 361, 368, 380, 736, 743]	-19.45 (± 28.80)	-18.76 (± 29.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 8 and 12 in the Patient's Assessment of TS-VAS

End point title	Change from Baseline to Weeks 4, 8 and 12 in the Patient's Assessment of TS-VAS

End point description:

The analysis population was the FAS. N is the number of participants analyzed with data available at each time point.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=395, 386, 391, 394, 788, 788]	1.14 (± 0.12)	1.68 (± 0.12)	1.77 (± 0.12)	1.82 (± 0.12)
Week 8 [N=380, 369, 380, 385, 754, 756]	1.50 (± 0.11)	2.16 (± 0.12)	2.09 (± 0.11)	2.20 (± 0.11)
Week 12 [N=370, 361, 366, 373, 736, 732]	1.47 (± 0.12)	2.24 (± 0.12)	2.23 (± 0.12)	2.32 (± 0.12)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: units on a scale				
least squares mean (standard error)				
Week 4 [N=395, 386, 391, 394, 788, 788]	2.06 (± 0.08)	2.13 (± 0.08)		
Week 8 [N=380, 369, 380, 385, 754, 756]	2.48 (± 0.08)	2.48 (± 0.08)		
Week 12 [N=370, 361, 366, 373, 736, 732]	2.58 (± 0.08)	2.63 (± 0.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Zero Incontinence Episodes per 24

Hours Using the Last 3 Diary Days at Weeks 4, 8, 12 and EoT	
End point title	Percentage of Participants with Zero Incontinence Episodes per 24 Hours Using the Last 3 Diary Days at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants with zero incontinence episodes per 24 hours postbaseline in the last 3 days prior to weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	410
Units: percentage of particpants				
number (not applicable)				
Week 4 [N=406, 406, 402, 402, 817, 810]	23.2	24.9	27.6	28.9
Week 8 [N=397, 385, 386, 386, 784, 769]	28.7	35.3	40.7	38.3
Week 12 [N=374, 369, 369, 379, 754, 750]	38.0	42.5	47.4	42.7
EoT [N=412, 409, 406, 413, 823, 816]	37.6	40.6	46.3	42.9

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of particpants				
number (not applicable)				
Week 4 [N=406, 406, 402, 402, 817, 810]	35.1	37.3		
Week 8 [N=397, 385, 386, 386, 784, 769]	45.3	48.2		
Week 12 [N=374, 369, 369, 379, 754, 750]	52.3	52.7		
EoT [N=412, 409, 406, 413, 823, 816]	50.7	52.2		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number

of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.035
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	1.69

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	1.81

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.16
upper limit	1.93

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	1.73

Secondary: Percentage of Participants with ≥ 10 Points Improvement from Baseline in the OAB-q Symptom Bother Score at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants with ≥ 10 Points Improvement from Baseline in the OAB-q Symptom Bother Score at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants with ≥ 10 points improvement from baseline to each visit (weeks 4, 8, 12 and EoT). The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=397, 388, 392, 394, 790, 789]	56.4	62.6	69.9	73.9

Week 8 [N=381, 370, 380, 385, 757, 761]	62.2	71.6	73.4	79.2
Week 12 [N=371, 362, 366, 374, 738, 734]	66.0	72.1	78.4	82.4
EoT [N=400, 392, 398, 399, 800, 795]	65.3	71.2	77.1	81.2

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=397, 388, 392, 394, 790, 789]	73.9	75.8		
Week 8 [N=381, 370, 380, 385, 757, 761]	83.9	82.8		
Week 12 [N=371, 362, 366, 374, 738, 734]	83.5	85.1		
EoT [N=400, 392, 398, 399, 800, 795]	82.8	84.3		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)
Statistical analysis description:	
Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline OAB-q subscale as a covariate.	
Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.224
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.69

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)
Statistical analysis description:	
Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline OAB-q subscale as a covariate.	

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.037
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	1.96

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline OAB-q subscale as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.47
upper limit	2.67

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline OAB-q subscale as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.65

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	2.26

Secondary: Percentage of Participants with ≥ 10 Points Improvement from Baseline in HRQL Total Score at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants with ≥ 10 Points Improvement from Baseline in HRQL Total Score at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants with ≥ 10 points improvement from baseline to each visit (weeks 4, 8, 12 and EoT). The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=397, 388, 392, 394, 790, 789]	45.3	52.8	59.7	61.7
Week 8 [N=381, 370, 380, 385, 757, 761]	51.2	62.2	65.3	66.2
Week 12 [N=371, 362, 366, 374, 738, 734]	57.7	62.4	69.1	71.7
EoT [N=400, 392, 398, 399, 800, 795]	56.8	61.0	68.3	71.2

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=397, 388, 392, 394, 790, 789]	62.9	61.3		
Week 8 [N=381, 370, 380, 385, 757, 761]	71.5	69.3		
Week 12 [N=371, 362, 366, 374, 738, 734]	76.3	71.8		
EoT [N=400, 392, 398, 399, 800, 795]	74.5	71.1		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline OAB-q subscale as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.077
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.72

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline OAB-q subscale as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.321
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.53

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline OAB-q subscale as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.46
upper limit	2.53

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline OAB-q subscale as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.294
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.53

Secondary: Percentage of Participants with 50% Reduction in Mean Number of Incontinence Episodes per 24 Hours at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants with 50% Reduction in Mean Number of Incontinence Episodes per 24 Hours at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants with ≥ 50% decrease from baseline in mean number of incontinence episodes per 24 hours at each time point (weeks 4, 8, 12 and EoT). The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=406, 406, 402, 402, 817, 810]	41.1	45.3	56.7	53.2
Week 8 [N=397, 385, 386, 386, 784, 769]	54.9	61.8	63.7	65.3
Week 12 [N=374, 369, 369, 379, 754, 750]	58.6	66.4	70.2	71.0
EoT [N=412, 409, 406, 413, 823, 816]	59.5	64.5	69.0	70.5

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=406, 406, 402, 402, 817, 810]	57.2	60.6		
Week 8 [N=397, 385, 386, 386, 784, 769]	69.8	70.6		
Week 12 [N=374, 369, 369, 379, 754, 750]	75.9	76.1		
EoT [N=412, 409, 406, 413, 823, 816]	74.5	75.7		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.251
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.17

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.53

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.107
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.64

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	2.07

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:
Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.08
upper limit	1.85

Secondary: Percentage of Participants with Micturition Frequency Normalization at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants with Micturition Frequency Normalization at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants with micturition frequency normalization was defined as any participant who had ≥ 8 micturitions/24 hours at baseline and < 8 micturitions/24 h postbaseline at weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. Participants with less < 8 micturitions per 24 hours at baseline was not included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=406, 406, 402, 402, 817, 810]	24.1	30.8	25.4	31.1
Week 8 [N=397, 385, 386, 386, 784, 769]	28.7	37.9	34.5	37.0
Week 12 [N=374, 369, 369, 379, 754, 750]	29.7	42.3	40.7	44.9
EoT [N=412, 409, 406, 413, 823, 816]	31.1	42.1	40.1	45.0

End point values	Solifenacin 5	Solifenacin 5		

	mg + mirabegron 25 mg	mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=406, 406, 402, 402, 817, 810]	36.0	37.7		
Week 8 [N=397, 385, 386, 386, 784, 769]	45.3	49.0		
Week 12 [N=374, 369, 369, 379, 754, 750]	50.8	53.1		
EoT [N=412, 409, 406, 413, 823, 816]	51.3	52.6		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.044
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.67

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.43

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.84

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours during the last 3 days as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.9

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of micturitions as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	2.08

Secondary: Percentage of Participants with Zero Incontinence Episodes per 24

Hours Using the Last 7 Diary Days at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants with Zero Incontinence Episodes per 24 Hours Using the Last 7 Diary Days at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants with zero incontinence episodes per 24 hours postbaseline in the last 7 days prior to weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=406, 406, 402, 402, 817, 810]	12.8	13.1	16.7	17.7
Week 8 [N=397, 385, 386, 386, 784, 769]	19.1	24.4	29.8	28.2
Week 12 [N=374, 369, 369, 379, 754, 750]	29.1	32.2	35.0	31.9
EoT [N=412, 409, 406, 413, 823, 816]	28.6	30.6	34.0	31.5

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=406, 406, 402, 402, 817, 810]	23.9	26.0		
Week 8 [N=397, 385, 386, 386, 784, 769]	36.6	38.4		
Week 12 [N=374, 369, 369, 379, 754, 750]	42.4	43.7		
EoT [N=412, 409, 406, 413, 823, 816]	40.9	43.1		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number

of incontinence episodes per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.92

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.24
upper limit	2.11

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.59

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.22
upper limit	2.07

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline mean number of incontinence episodes per 24 hours as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	2.04

Secondary: Percentage of Participants with ≥ 1 Point Improvement from Baseline in PPBC at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants with ≥ 1 Point Improvement from Baseline in PPBC at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants with ≥ 1 point improvement from baseline in PPBC at weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=397, 388, 393, 394, 791, 791]	48.9	52.8	60.3	58.1

Week 8 [N=381, 372, 380, 385, 758, 761]	56.4	65.3	69.7	72.7
Week 12 [N=371, 362, 366, 375, 739, 735]	59.8	66.9	73.8	74.1
EoT [N=400, 393, 398, 399, 801, 795]	59.8	65.4	72.4	71.9

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=397, 388, 393, 394, 791, 791]	63.1	62.7		
Week 8 [N=381, 372, 380, 385, 758, 761]	71.6	75.4		
Week 12 [N=371, 362, 366, 375, 739, 735]	76.6	80.0		
EoT [N=400, 393, 398, 399, 801, 795]	75.7	78.4		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline PPBC as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.065
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.78

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline PPBC as a covariate.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.24
upper limit	2.27

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline PPBC as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.32
upper limit	2.36

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline PPBC as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.51

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.12
upper limit	2.04

Secondary: Percentage of Participants with Major (≥ 2 points) Improvement from Baseline in PPBC at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants with Major (≥ 2 points) Improvement from Baseline in PPBC at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants with a major (≥ 2 points) improvement from baseline in PPBC at weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=397, 388, 393, 394, 791, 791]	15.9	20.6	22.4	27.4
Week 8 [N=381, 372, 380, 385, 758, 761]	27.0	33.3	35.0	40.5
Week 12 [N=371, 362, 366, 375, 739, 735]	29.6	39.0	42.3	44.5
EoT [N=400, 393, 398, 399, 801, 795]	29.5	37.2	40.7	42.6

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=397, 388, 393, 394, 791, 791]	31.1	31.1		
Week 8 [N=381, 372, 380, 385, 758, 761]	42.7	46.4		
Week 12 [N=371, 362, 366, 375, 739, 735]	50.7	52.9		
EoT [N=400, 393, 398, 399, 801, 795]	49.7	51.2		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)
Statistical analysis description:	
Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline PPBC as a covariate.	
Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.87

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)
Statistical analysis description:	
Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline PPBC as a covariate.	
Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.28
upper limit	2.17

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline PPBC as a covariate.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.34
upper limit	2.3

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors and baseline PPBC as a covariate.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.29
upper limit	2.19

Secondary: Percentage of Participants Who Were Double Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours and at least 10 Points Improvement on OAB-q Symptom Bother Scale) at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants Who Were Double Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours and at least 10 Points Improvement on OAB-q Symptom Bother Scale) at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants considered as double responders, defined as participants with 50% reduction in mean number of incontinence episodes per 24 hours compared to baseline and minimal important difference reached (improvement by ≥ 10 points) on the OAB-q Symptom Bother score at weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 385, 387, 385, 784, 778]	28.6	34.8	45.7	44.9
Week 8 [N=374, 366, 375, 372, 750, 742]	39.8	50.0	51.5	56.5
Week 12 [N=360, 350, 355, 363, 727, 721]	45.0	55.7	59.4	63.1
EoT [N=396, 391, 395, 398, 798, 790]	45.2	54.0	58.2	62.6

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 385, 387, 385, 784, 778]	47.8	52.3		
Week 8 [N=374, 366, 375, 372, 750, 742]	63.1	63.5		
Week 12 [N=360, 350, 355, 363, 727, 721]	66.7	69.5		
EoT [N=396, 391, 395, 398, 798, 790]	65.2	68.2		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline OAB-q symptom bother scale as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.381
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.45

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline OAB-q symptom bother scale as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.04
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.7

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline OAB-q symptom bother scale as covariates.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.56

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	2

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline OAB-q symptom bother scale as covariates.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	2.03

Secondary: Percentage of Participants Who Were Double Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours and at least 10 Points Improvement on OAB-q HRQL Total Score) at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants Who Were Double Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours and at least 10 Points Improvement on OAB-q HRQL Total Score) at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants considered as double responders, defined as participants with 50% reduction in mean number of incontinence episodes per 24 hours compared to baseline and minimal important difference reached (improvement by ≥ 10 points) on the OAB-q HRQL total score at weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 385, 387, 385, 784, 778]	23.2	28.3	39.8	37.7
Week 8 [N=374, 366, 375, 372, 750, 742]	32.9	43.2	46.1	48.4
Week 12 [N=360, 350, 355, 363, 727, 721]	39.2	48.3	53.5	54.8
EoT [N=396, 391, 395, 398, 798, 790]	39.1	46.0	52.9	54.0

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 385, 387, 385, 784, 778]	40.4	40.5		
Week 8 [N=374, 366, 375, 372, 750, 742]	54.1	53.0		
Week 12 [N=360, 350, 355, 363, 727, 721]	61.6	59.2		
EoT [N=396, 391, 395, 398, 798, 790]	59.0	58.2		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline OAB-q HRQL total score as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.095
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.59

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)
Statistical analysis description:	
Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline OAB-q HRQL total score as covariates.	
Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.62

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)
Statistical analysis description:	
Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline OAB-q HRQL total score as covariates.	
Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.29
upper limit	2.13

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)
Statistical analysis description:	
Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline OAB-q HRQL total score as covariates.	
Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg

Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.067
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.63

Secondary: Percentage of Participants Who Were Double Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours and at least 1 Point Improvement on PPBC) at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants Who Were Double Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours and at least 1 Point Improvement on PPBC) at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants considered as double responders, defined as participants with 50% reduction in mean number of incontinence episodes per 24 hours compared to baseline and ≥ 1 point improvement from baseline in PPBC at weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 384, 387, 385, 785, 780]	23.2	27.9	37.7	34.5
Week 8 [N=374, 367, 375, 372, 751, 742]	35.6	44.7	50.1	51.3
Week 12 [N=360, 350, 355, 364, 728, 722]	40.6	51.7	54.9	56.9
EoT [N=396, 392, 395, 398, 799, 790]	40.9	48.5	53.9	56.0

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 384, 387, 385, 785, 780]	39.9	42.9		
Week 8 [N=374, 367, 375, 372, 751, 742]	53.8	57.7		
Week 12 [N=360, 350, 355, 364, 728, 722]	62.0	65.4		
EoT [N=396, 392, 395, 398, 799, 790]	59.9	63.8		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline PPBC as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.21
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.52

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline PPBC as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.46

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.89

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline PPBC as covariates.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	2.06

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours and baseline PPBC as covariates.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	2.05

Secondary: Percentage of Participants Who Were Triple Responders (50%

Reduction in Mean Number of Incontinence Episodes per 24 Hours, at least 10 Points Improvement on OAB-q Symptom Bother Scale and at least 1 Point Improvement on PPBC) at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants Who Were Triple Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours, at least 10 Points Improvement on OAB-q Symptom Bother Scale and at least 1 Point Improvement on PPBC) at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants considered as triple responders, defined as participants with 50% reduction in mean number of incontinence episodes per 24 hours compared to baseline, minimal important difference reached (improvement by ≥ 10 points) on the OAB-q Symptom Bother score, and ≥ 1 point improvement from baseline in PPBC at weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 384, 387, 385, 784, 778]	17.8	24.0	33.6	31.4
Week 8 [N=374, 366, 375, 372, 750, 742]	29.7	41.3	43.2	47.8
Week 12 [N=360, 350, 355, 363, 727, 721]	35.8	47.7	49.6	54.5
EoT [N=396, 391, 395, 398, 798, 790]	36.1	45.0	48.4	53.3

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 384, 387, 385, 784, 778]	37.5	40.2		
Week 8 [N=374, 366, 375, 372, 750, 742]	51.6	54.7		
Week 12 [N=360, 350, 355, 363, 727, 721]	58.2	62.0		
EoT [N=396, 391, 395, 398, 798, 790]	56.3	60.3		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours, baseline OAB-q symptom bother scale and baseline PPBC as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.335
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.46

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours, baseline OAB-q symptom bother scale and baseline PPBC as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	1.81

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours, baseline OAB-q symptom bother scale and baseline PPBC as covariates.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg

Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	2.02

Statistical analysis title	Odds ratio vs. Mirabegron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours, baseline OAB-q symptom bother scale and baseline PPBC as covariates.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.33
upper limit	2.21

Secondary: Percentage of Participants Who Were Triple Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours, at least 10 Points Improvement on OAB-q HRQL Total Score and at least 1 Point Improvement on PPBC) at Weeks 4, 8, 12 and EoT

End point title	Percentage of Participants Who Were Triple Responders (50% Reduction in Mean Number of Incontinence Episodes per 24 Hours, at least 10 Points Improvement on OAB-q HRQL Total Score and at least 1 Point Improvement on PPBC) at Weeks 4, 8, 12 and EoT

End point description:

The percentage of participants considered as triple responders, defined as participants with 50% reduction in mean number of incontinence episodes per 24 hours compared to baseline, minimal important difference reached (improvement by ≥ 10 points) on the HRQL total score, and ≥ 1 point improvement from baseline in PPBC at weeks 4, 8, 12 and EoT. The analysis population was the FAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EOT.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	418	410	411	415
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 384, 387, 385, 784, 778]	15.2	20.6	30.0	28.6
Week 8 [N=374, 366, 375, 372, 750, 742]	24.9	36.9	38.9	43.0
Week 12 [N=360, 350, 355, 362, 727, 721]	33.3	42.0	45.6	49.9
EoT [N=396, 391, 395, 398, 798, 790]	33.3	39.1	44.8	49.2

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	827	827		
Units: percentage of participants				
number (not applicable)				
Week 4 [N=388, 384, 387, 385, 784, 778]	32.7	33.4		
Week 8 [N=374, 366, 375, 372, 750, 742]	46.3	46.8		
Week 12 [N=360, 350, 355, 362, 727, 721]	54.5	54.2		
EoT [N=396, 391, 395, 398, 798, 790]	51.6	52.8		

Statistical analyses

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (1) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours, baseline OAB-q HRQL total score and baseline PPBC as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 25 mg

Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.416
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.43

Statistical analysis title	Odds ratio vs. Solifenacin 5 mg (2) (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours, baseline OAB-q HRQL total score and baseline PPBC as covariates.

Comparison groups	Solifenacin 5 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.105
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.59

Statistical analysis title	Odds ratio vs. Mirabegron 25 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours, baseline OAB-q HRQL total score and baseline PPBC as covariates.

Comparison groups	Mirabegron 25 mg v Solifenacin 5 mg + mirabegron 25 mg
Number of subjects included in analysis	1237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.66

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.28
upper limit	2.16

Statistical analysis title	Odds ratio vs. Mirabgeron 50 mg (EoT)

Statistical analysis description:

Odds ratio from a logistic regression model including treatment group, sex, age group (<65, >=65 years), previous OAB medication (yes, no) and geographic region as factors, and baseline mean number of incontinence episodes per 24 hours, baseline OAB-q HRQL total score and baseline PPBC as covariates.

Comparison groups	Mirabegron 50 mg v Solifenacin 5 mg + mirabegron 50 mg
Number of subjects included in analysis	1238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Logistic regression
Parameter estimate	Odds ratio (OR)
Point estimate	1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.12
upper limit	1.87

Secondary: Number of Participants with Treatment-Emergent Adverse Events (TEAEs)

End point title	Number of Participants with Treatment-Emergent Adverse Events (TEAEs)

End point description:

A TEAE referred to an adverse event (AE; defined as any untoward medical occurrence in a participant administered a study drug or who had undergone study procedures and did not necessarily have a causal relationship with this treatment) which started or worsened in the period from first double-blind medication intake until 14 days after the last double-blind medication intake. Serious TEAEs with a start date reported until 30 days after the last double-blind medication intake were also summarized as TEAEs, and also included serious TEAEs upgraded by the sponsor based on review of the sponsor's list of Always Serious terms if any upgrade was done. Drug-related TEAEs may be possible or probable, as assessed by the investigator, or records where relationship is missing. The analysis population was the Safety Analysis Set (SAF), which comprised all randomized participants who received ≥ 1 dose of double-blind treatment and excluded participants from one site.

End point type	Secondary

End point timeframe:

From first dose of double-blind study drug up to 30 days after last dose of double-blind study drug (up to 16 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	429	423	422	423
Units: participants				
Any TEAE	145	135	147	149
Drug-related TEAEs	45	37	52	63
Deaths	0	0	0	0
Serious TEAEs	8	6	5	3
Drug-related serious TEAEs	0	1	1	0
TEAEs leading to discontinuation	9	7	10	7
Drug-related TEAEs leading to discontinuation	7	4	6	5

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	853	848		
Units: participants				
Any TEAE	345	314		
Drug-related TEAEs	157	150		
Deaths	0	0		
Serious TEAEs	12	19		
Drug-related serious TEAEs	2	3		
TEAEs leading to discontinuation	20	22		
Drug-related TEAEs leading to discontinuation	17	19		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 8, 12 and EoT in Postvoid Residual (PVR) Volume

End point title	Change from Baseline to Weeks 4, 8, 12 and EoT in Postvoid Residual (PVR) Volume

End point description:

PVR volume was assessed by ultrasonography or a bladder scanner. The analysis population was the SAF. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 8, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	429	423	422	423
Units: mL				
arithmetic mean (standard deviation)				
Week 4 [N=408, 397, 398, 412, 815, 812]	-0.8 (± 29.9)	1.6 (± 28.0)	-2.1 (± 29.7)	5.8 (± 35.6)
Week 8 [N=393, 378, 383, 393, 779, 784]	-1.9 (± 28.6)	-0.4 (± 29.8)	-0.6 (± 34.4)	5.4 (± 35.2)
Week 12 [N=382, 376, 370, 383, 766, 763]	-1.0 (± 29.9)	1.0 (± 29.8)	0.0 (± 30.1)	4.7 (± 33.1)
EoT [N=410, 401, 404, 414, 821, 815]	-1.0 (± 29.4)	0.7 (± 29.1)	-0.8 (± 30.0)	4.8 (± 33.3)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	853	848		
Units: mL				
arithmetic mean (standard deviation)				
Week 4 [N=408, 397, 398, 412, 815, 812]	7.2 (± 47.7)	10.6 (± 51.1)		
Week 8 [N=393, 378, 383, 393, 779, 784]	7.0 (± 37.4)	9.9 (± 46.0)		
Week 12 [N=382, 376, 370, 383, 766, 763]	7.9 (± 44.4)	9.6 (± 50.1)		
EoT [N=410, 401, 404, 414, 821, 815]	9.0 (± 55.0)	1.5 (± 32.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in Mean 24 hours (h), Mean Daytime and Mean Nighttime Systolic Blood Pressure (SBP)

End point title	Change from Baseline to Weeks 4, 12 and EoT in Mean 24 hours (h), Mean Daytime and Mean Nighttime Systolic Blood Pressure (SBP)

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ambulatory blood pressure monitoring (ABPM) device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. The analysis population was the ABPM analysis set (ABPMAS) which consisted of all participants in the SAF for whom at least 1 ABPM variable (mean value at tmax (4-6h), mean 24-h value, maximum 1-h change from time-matched baseline value, mean daytime value, mean nighttime value or peak/trough difference) could be calculated at baseline and postbaseline visit. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: mmHg				
least squares mean (standard error)				
Week 4 24-hour mean [N=76, 66, 67, 72, 141, 157]	-1.00 (± 1.22)	-2.04 (± 1.31)	0.96 (± 1.30)	1.03 (± 1.26)
Week 4 mean daytime [N=72, 60, 62, 60, 129, 147]	-1.55 (± 1.22)	-1.19 (± 1.33)	-0.67 (± 1.31)	-1.13 (± 1.34)
Week 4 mean nighttime [N=82, 74, 75, 72, 147, 161]	-0.51 (± 1.38)	-1.14 (± 1.46)	1.42 (± 1.44)	0.41 (± 1.47)
Week 12 24-hour mean [N=67, 62, 63, 60, 121, 139]	-1.97 (± 1.37)	-2.70 (± 1.42)	-1.75 (± 1.41)	0.40 (± 1.45)
Week 12 mean daytime [N=65, 56, 55, 53, 106, 116]	-2.22 (± 1.37)	-2.53 (± 1.46)	-2.14 (± 1.48)	-2.09 (± 1.50)
Week 12 mean nighttime [N=75, 64, 71, 65, 132,146]	-1.03 (± 1.64)	-2.81 (± 1.77)	-0.77 (± 1.68)	1.31 (± 1.76)
EoT 24-hour mean [N=80, 73, 76, 78, 150, 168]	-1.73 (± 1.24)	-3.44 (± 1.29)	-1.14 (± 1.27)	0.37 (± 1.25)
EoT mean daytime [N=78, 67, 69, 69, 137, 153]	-2.01 (± 1.22)	-3.29 (± 1.31)	-1.92 (± 1.30)	-2.17 (± 1.30)
EoT mean nighttime [N=88, 80, 82, 82, 160, 175]	-1.00 (± 1.47)	-3.48 (± 1.54)	-0.60 (± 1.52)	1.42 (± 1.52)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: mmHg				
least squares mean (standard error)				
Week 4 24-hour mean [N=76, 66, 67, 72, 141, 157]	-0.85 (± 0.90)	0.31 (± 0.85)		
Week 4 mean daytime [N=72, 60, 62, 60, 129, 147]	-1.63 (± 0.91)	-0.53 (± 0.85)		
Week 4 mean nighttime [N=82, 74, 75, 72, 147, 161]	1.14 (± 1.03)	0.54 (± 0.98)		
Week 12 24-hour mean [N=67, 62, 63, 60, 121, 139]	-0.71 (± 1.02)	0.40 (± 0.95)		
Week 12 mean daytime [N=65, 56, 55, 53, 106, 116]	-0.39 (± 1.06)	-0.71 (± 1.02)		
Week 12 mean nighttime [N=75, 64, 71, 65, 132,146]	0.11 (± 1.23)	0.79 (± 1.17)		
EoT 24-hour mean [N=80, 73, 76, 78, 150, 168]	-0.52 (± 0.90)	-0.08 (± 0.85)		
EoT mean daytime [N=78, 67, 69, 69, 137, 153]	-0.68 (± 0.92)	-1.28 (± 0.87)		
EoT mean nighttime [N=88, 80, 82, 82, 160, 175]	0.41 (± 1.09)	0.91 (± 1.04)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in Mean 24-h, Mean Daytime and Mean Nighttime Diastolic Blood Pressure (DBP)

End point title	Change from Baseline to Weeks 4, 12 and EoT in Mean 24-h, Mean Daytime and Mean Nighttime Diastolic Blood Pressure (DBP)

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: mmHg				
least squares mean (standard error)				
Week 4 24-hour mean [N=76, 66, 67, 72, 141, 157]	-0.70 (± 0.50)	-0.86 (± 0.54)	0.22 (± 0.54)	0.25 (± 0.52)
Week 4 mean daytime [N=72, 60, 62, 60, 129, 147]	-1.25 (± 0.53)	-0.36 (± 0.58)	-0.33 (± 0.57)	-0.77 (± 0.58)
Week 4 mean nighttime [N=82, 74, 75, 72, 147, 161]	-0.12 (± 0.59)	-0.97 (± 0.62)	0.40 (± 0.62)	0.48 (± 0.63)
Week 12 24-hour mean [N=67, 62, 63, 60, 121, 139]	-0.80 (± 0.56)	-0.93 (± 0.58)	-0.19 (± 0.57)	0.43 (± 0.59)
Week 12 mean daytime [N=65, 56, 55, 53, 106, 116]	-0.85 (± 0.60)	-0.54 (± 0.64)	-0.40 (± 0.65)	-0.33 (± 0.66)
Week 12 mean nighttime [N=75, 64, 71, 65, 132,146]	-0.49 (± 0.66)	-1.39 (± 0.71)	-0.03 (± 0.68)	0.92 (± 0.71)
EoT 24-hour mean [N=80, 73, 76, 78, 150, 168]	-0.96 (± 0.51)	-1.41 (± 0.53)	-0.11 (± 0.52)	0.05 (± 0.52)
EoT mean daytime [N=78, 67, 69, 69, 137, 153]	-1.17 (± 0.53)	-0.98 (± 0.58)	-0.69 (± 0.57)	-0.79 (± 0.57)
EoT mean nighttime [N=88, 80, 82, 82, 160, 178]	-0.41 (± 0.60)	-2.00 (± 0.63)	0.08 (± 0.63)	0.71 (± 0.63)

End point values	Solifenacin 5 mg +	Solifenacin 5 mg +		

	mirabegron 25 mg	mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: mmHg				
least squares mean (standard error)				
Week 4 24-hour mean [N=76, 66, 67, 72, 141, 157]	0.03 (± 0.37)	0.38 (± 0.35)		
Week 4 mean daytime [N=72, 60, 62, 60, 129, 147]	-0.40 (± 0.40)	0.07 (± 0.37)		
Week 4 mean nighttime [N=82, 74, 75, 72, 147, 161]	0.93 (± 0.44)	0.47 (± 0.42)		
Week 12 24-hour mean [N=67, 62, 63, 60, 121, 139]	-0.37 (± 0.41)	0.31 (± 0.39)		
Week 12 mean daytime [N=65, 56, 55, 53, 106, 116]	-0.06 (± 0.46)	-0.18 (± 0.44)		
Week 12 mean nighttime [N=75, 64, 71, 65, 132,146]	0.23 (± 0.49)	0.49 (± 0.47)		
EoT 24-hour mean [N=80, 73, 76, 78, 150, 168]	-0.02 (± 0.37)	0.25 (± 0.35)		
EoT mean daytime [N=78, 67, 69, 69, 137, 153]	-0.18 (± 0.40)	-0.36 (± 0.38)		
EoT mean nighttime [N=88, 80, 82, 82, 160, 178]	0.56 (± 0.45)	0.61 (± 0.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in Mean 24-h, Mean Daytime and Mean Nighttime Pulse Rate

End point title	Change from Baseline to Weeks 4, 12 and EoT in Mean 24-h, Mean Daytime and Mean Nighttime Pulse Rate

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: beats per minute (bpm)				
least squares mean (standard error)				
Week 4 24-hour mean [N=76, 66, 67, 72, 141, 157]	-0.83 (± 0.63)	1.14 (± 0.68)	2.32 (± 0.67)	0.36 (± 0.65)
Week 4 mean daytime [N=72, 60, 62, 60, 129, 147]	-0.70 (± 0.73)	1.19 (± 0.79)	3.52 (± 0.78)	0.37 (± 0.80)

Week 4 mean nighttime [N=82, 74, 75, 72, 147, 161]	-0.72 (± 0.68)	0.98 (± 0.71)	1.77 (± 0.70)	1.09 (± 0.72)
Week 12 24-hour mean [N=67, 62, 63, 60, 121, 189]	0.70 (± 0.72)	0.38 (± 0.74)	1.19 (± 0.74)	0.12 (± 0.76)
Week 12 mean daytime [N=65, 56, 55, 53, 106, 116]	0.89 (± 0.82)	0.25 (± 0.88)	2.12 (± 0.89)	-0.13 (± 0.90)
Week 12 mean nighttime [N=75, 64, 71, 65, 132,146]	0.34 (± 0.71)	0.21 (± 0.77)	0.19 (± 0.73)	0.06 (± 0.76)
EoT 24-hour mean [N=80, 73, 76, 78, 150, 168]	0.41 (± 0.65)	0.63 (± 0.68)	1.67 (± 0.67)	0.02 (± 0.66)
EoT mean daytime [N=78, 67, 69, 69, 137, 153]	0.45 (± 0.74)	0.37 (± 0.80)	2.64 (± 0.79)	-0.07 (± 0.79)
EoT mean nighttime [N=88, 80, 82, 82, 160, 175]	0.39 (± 0.66)	0.82 (± 0.69)	0.75 (± 0.68)	0.45 (± 0.68)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: beats per minute (bpm)				
least squares mean (standard error)				
Week 4 24-hour mean [N=76, 66, 67, 72, 141, 157]	0.40 (± 0.46)	0.69 (± 0.44)		
Week 4 mean daytime [N=72, 60, 62, 60, 129, 147]	-0.05 (± 0.54)	0.61 (± 0.51)		
Week 4 mean nighttime [N=82, 74, 75, 72, 147, 161]	0.86 (± 0.50)	0.86 (± 0.48)		
Week 12 24-hour mean [N=67, 62, 63, 60, 121, 189]	0.94 (± 0.53)	1.44 (± 0.50)		
Week 12 mean daytime [N=65, 56, 55, 53, 106, 116]	0.84 (± 0.64)	1.36 (± 0.61)		
Week 12 mean nighttime [N=75, 64, 71, 65, 132,146]	0.76 (± 0.53)	1.52 (± 0.51)		
EoT 24-hour mean [N=80, 73, 76, 78, 150, 168]	0.85 (± 0.47)	1.52 (± 0.45)		
EoT mean daytime [N=78, 67, 69, 69, 137, 153]	0.32 (± 0.56)	1.24 (± 0.53)		
EoT mean nighttime [N=88, 80, 82, 82, 160, 175]	1.21 (± 0.49)	1.64 (± 0.47)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in Mean SBP in the Time to Maximum Concentration (Tmax) Window

End point title	Change from Baseline to Weeks 4, 12 and EoT in Mean SBP in the Time to Maximum Concentration (Tmax) Window

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. Tmax window of mirabegron and solifenacin was from 4-6 hours postdose. The analysis population was the

ABPMAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=77, 63, 73, 72, 142, 160]	-2.71 (± 1.68)	0.34 (± 1.86)	-1.03 (± 1.72)	-1.77 (± 1.74)
Week 12 [N=72, 60, 64, 59, 130, 131]	-4.86 (± 1.78)	-2.13 (± 1.95)	-1.64 (± 1.88)	-3.15 (± 1.96)
EoT [N=83, 75, 79, 78, 157, 169]	-4.40 (± 1.60)	-2.19 (± 1.68)	-1.94 (± 1.64)	-3.64 (± 1.65)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=77, 63, 73, 72, 142, 160]	-1.55 (± 1.23)	-1.47 (± 1.17)		
Week 12 [N=72, 60, 64, 59, 130, 131]	-0.26 (± 1.32)	0.60 (± 1.32)		
EoT [N=83, 75, 79, 78, 157, 169]	-0.61 (± 1.16)	-0.98 (± 1.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in Mean DBP in the Tmax Window

End point title	Change from Baseline to Weeks 4, 12 and EoT in Mean DBP in the Tmax Window

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. Tmax window of mirabegron and solifenacin was from 4-6 hours postdose. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=77, 63, 73, 72, 142, 160]	-1.24 (± 0.84)	0.09 (± 0.93)	-0.65 (± 0.86)	-0.48 (± 0.87)
Week 12 [N=72, 60, 64, 59, 130, 131]	-1.74 (± 0.92)	-0.45 (± 1.00)	-0.31 (± 0.97)	-1.49 (± 1.01)
EoT [N=83, 75, 79, 78, 157, 169]	-1.85 (± 0.84)	-0.71 (± 0.88)	-0.71 (± 0.85)	-1.22 (± 0.86)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=77, 63, 73, 72, 142, 160]	-0.22 (± 0.62)	-0.71 (± 0.58)		
Week 12 [N=72, 60, 64, 59, 130, 131]	0.48 (± 0.68)	-0.03 (± 0.68)		
EoT [N=83, 75, 79, 78, 157, 169]	0.44 (± 0.61)	-0.80 (± 0.59)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in Mean Pulse Rate in the Tmax Window

End point title	Change from Baseline to Weeks 4, 12 and EoT in Mean Pulse Rate in the Tmax Window

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. Tmax window of mirabegron and solifenacin was from 4-6 hours postdose. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: bpm				
least squares mean (standard error)				
Week 4 [N=77, 63, 73, 72, 142, 160]	0.02 (± 1.08)	2.39 (± 1.19)	3.68 (± 1.10)	0.47 (± 1.11)
Week 12 [N=72, 60, 64, 59, 130, 131]	0.10 (± 1.10)	1.22 (± 1.20)	1.87 (± 1.16)	0.37 (± 1.21)
EoT [N=83, 75, 79, 78, 157, 169]	-0.43 (± 1.05)	0.82 (± 1.10)	3.41 (± 1.07)	-1.25 (± 1.08)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: bpm				
least squares mean (standard error)				
Week 4 [N=77, 63, 73, 72, 142, 160]	-0.91 (± 0.79)	0.67 (± 0.75)		
Week 12 [N=72, 60, 64, 59, 130, 131]	0.15 (± 0.81)	1.39 (± 0.81)		
EoT [N=83, 75, 79, 78, 157, 169]	0.34 (± 0.76)	1.25 (± 0.73)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum 1-hour Change from Time-matched Baseline in SBP at Weeks 4, 12 and EoT

End point title	Maximum 1-hour Change from Time-matched Baseline in SBP at Weeks 4, 12 and EoT

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. Only participants with an increase (i.e., maximum 1-hour change from time-matched baseline ≥ 0 mmHg) were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	34.05 (± 2.06)	31.14 (± 2.20)	38.20 (± 2.19)	35.16 (± 2.11)

Week 12 [N=67, 62, 63, 60, 121, 139]	33.21 (± 2.30)	30.68 (± 2.38)	32.88 (± 2.36)	35.11 (± 2.42)
EoT [N=80, 73, 76, 78, 150, 168]	34.98 (± 2.11)	30.65 (± 2.20)	33.53 (± 2.16)	34.95 (± 2.14)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	32.88 (± 1.51)	32.80 (± 1.43)		
Week 12 [N=67, 62, 63, 60, 121, 139]	33.53 (± 1.70)	32.82 (± 1.59)		
EoT [N=80, 73, 76, 78, 150, 168]	34.70 (± 1.54)	32.55 (± 1.45)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum 1-hour Change from Time-matched Baseline in DBP at Weeks 4, 12 and EoT

End point title	Maximum 1-hour Change from Time-matched Baseline in DBP at Weeks 4, 12 and EoT

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. Only participants with an increase (i.e., maximum 1-hour change from time-matched baseline ≥ 0 mmHg) were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	18.78 (± 1.27)	19.15 (± 1.36)	20.41 (± 1.35)	20.02 (± 1.31)
Week 12 [N=67, 62, 63, 60, 121, 139]	19.68 (± 1.23)	19.52 (± 1.28)	20.41 (± 1.27)	21.18 (± 1.30)
EoT [N=80, 73, 76, 78, 150, 168]	20.29 (± 1.16)	19.29 (± 1.22)	20.71 (± 1.19)	20.47 (± 1.18)

End point values	Solifenacin 5	Solifenacin 5		

	mg + mirabegron 25 mg	mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	20.74 (± 0.93)	20.27 (± 0.88)		
Week 12 [N=67, 62, 63, 60, 121, 139]	19.26 (± 0.92)	20.01 (± 0.85)		
EoT [N=80, 73, 76, 78, 150, 168]	20.29 (± 0.85)	20.36 (± 0.80)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum 1-hour Change from Time-matched Baseline in Pulse Rate at Weeks 4, 12 and EoT

End point title	Maximum 1-hour Change from Time-matched Baseline in Pulse Rate at Weeks 4, 12 and EoT

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. Only participants with an increase (i.e., maximum 1-hour change from time-matched baseline ≥ 0 bpm) were included in the analysis. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: bpm				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	22.34 (± 1.35)	23.86 (± 1.44)	25.12 (± 1.43)	24.28 (± 1.38)
Week 12 [N=67, 62, 63, 60, 121, 139]	22.63 (± 1.42)	23.54 (± 1.47)	26.03 (± 1.46)	23.52 (± 1.50)
EoT [N=80, 73, 76, 78, 150, 168]	23.01 (± 1.31)	24.12 (± 1.37)	26.23 (± 1.34)	23.33 (± 1.33)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: bpm				
least squares mean (standard error)				

Week 4 [N=76, 66, 67, 72, 141, 157]	21.48 (± 0.99)	21.80 (± 0.94)		
Week 12 [N=67, 62, 63, 60, 121, 139]	22.60 (± 1.05)	24.08 (± 0.98)		
EoT [N=80, 73, 76, 78, 150, 168]	22.66 (± 0.96)	24.14 (± 0.90)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in SBP Peak/Trough Difference

End point title	Change from Baseline to Weeks 4, 12 and EoT in SBP Peak/Trough Difference

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. Peak/trough difference was defined as the difference between the highest 1-h to lowest 1-h average per participant per visit. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	-0.71 (± 1.86)	0.14 (± 1.99)	-0.69 (± 1.98)	0.85 (± 1.91)
Week 12 [N=67, 62, 63, 60, 121, 139]	1.18 (± 1.98)	-2.45 (± 2.05)	-4.55 (± 2.03)	-1.63 (± 2.08)
EoT [N=80, 73, 76, 78, 150, 168]	1.15 (± 1.83)	-1.38 (± 1.91)	-2.30 (± 1.87)	-0.97 (± 1.85)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: mmHg				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	-1.61 (± 1.36)	0.41 (± 1.29)		
Week 12 [N=67, 62, 63, 60, 121, 139]	0.68 (± 1.47)	0.62 (± 1.37)		
EoT [N=80, 73, 76, 78, 150, 168]	0.25 (± 1.33)	0.68 (± 1.26)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in DBP Peak/Trough Difference

End point title	Change from Baseline to Weeks 4, 12 and EoT in DBP Peak/Trough Difference

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. Peak/trough difference was defined as the difference between the highest 1-h to lowest 1-h average per participant per visit. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: nnHg				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	-0.76 (± 1.31)	-1.08 (± 1.40)	-0.20 (± 1.39)	-1.60 (± 1.34)
Week 12 [N=67, 62, 63, 60, 121, 139]	0.53 (± 1.30)	0.15 (± 1.34)	-1.90 (± 1.33)	-0.66 (± 1.36)
EoT [N=80, 73, 76, 78, 150, 168]	0.87 (± 1.23)	0.27 (± 1.28)	-0.96 (± 1.26)	-1.67 (± 1.24)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: nnHg				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	0.39 (± 0.96)	-0.56 (± 0.91)		
Week 12 [N=67, 62, 63, 60, 121, 139]	-1.24 (± 0.96)	0.46 (± 0.90)		
EoT [N=80, 73, 76, 78, 150, 168]	-0.98 (± 0.89)	0.52 (± 0.85)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Weeks 4, 12 and EoT in Pulse Rate Peak/Trough Difference

End point title	Change from Baseline to Weeks 4, 12 and EoT in Pulse Rate

	Peak/Trough Difference

End point description:

Vital signs (blood pressure and pulse rate) were monitored using an ABPM device placed on the upper arm followed by intake of the double-blind study medication and worn for at least 24 hours. Peak/trough difference was defined as the difference between the highest 1-h to lowest 1-h average per participant per visit. The analysis population was the ABPMAS. N is the number of participants analyzed with data available at each time point. LOCF was used for EoT.

End point type	Secondary

End point timeframe:

Baseline and Weeks 4, 12 and EoT (up to 12 weeks)

End point values	Placebo	Mirabegron 25 mg	Mirabegron 50 mg	Solifenacin 5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	85	87	86
Units: bpm				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	1.16 (± 1.38)	0.46 (± 1.48)	1.54 (± 1.46)	0.78 (± 1.41)
Week 12 [N=67, 62, 63, 60, 121, 139]	3.35 (± 1.45)	-0.04 (± 1.50)	1.15 (± 1.49)	3.49 (± 1.53)
EoT [N=80, 73, 76, 78, 150, 168]	2.48 (± 1.32)	0.45 (± 1.37)	1.14 (± 1.35)	3.16 (± 1.33)

End point values	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	189		
Units: bpm				
least squares mean (standard error)				
Week 4 [N=76, 66, 67, 72, 141, 157]	-0.68 (± 1.01)	-0.51 (± 0.96)		
Week 12 [N=67, 62, 63, 60, 121, 139]	-0.53 (± 1.07)	1.48 (± 1.00)		
EoT [N=80, 73, 76, 78, 150, 168]	-0.02 (± 0.96)	1.80 (± 0.91)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose of double-blind study drug up to 30 days after last dose of double-blind study drug (up to 16 weeks)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants who received matching placebo once a day for 12 weeks.	
Reporting group title	Mirabegron 25 mg
Reporting group description:	
Participants who received mirabegron 25 mg once a day for 12 weeks.	
Reporting group title	Mirabegron 50 mg
Reporting group description:	
Participants who received mirabegron 50 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg
Reporting group description:	
Participants who received solifenacin 5 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg + mirabegron 25 mg
Reporting group description:	
Participants who received solifenacin 5 mg and mirabegron 25 mg once a day for 12 weeks.	
Reporting group title	Solifenacin 5 mg + mirabegron 50 mg
Reporting group description:	
Participants who received solifenacin 5 mg and mirabegron 50 mg once a day for 12 weeks.	

Serious adverse events	Placebo	Mirabegron 25 mg	Mirabegron 50 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 429 (1.86%)	6 / 423 (1.42%)	5 / 422 (1.18%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			

subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	1 / 422 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	1 / 422 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Renal stone removal			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Apnoea			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiccups			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 429 (0.00%)	1 / 423 (0.24%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			

subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 429 (0.00%)	1 / 423 (0.24%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 429 (0.00%)	1 / 423 (0.24%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Cerebral haemorrhage			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Grand mal convulsion			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	1 / 422 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Otorrhoea			
subjects affected / exposed	0 / 429 (0.00%)	1 / 423 (0.24%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	1 / 422 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis toxic			
subjects affected / exposed	0 / 429 (0.00%)	1 / 423 (0.24%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Rotator cuff syndrome			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	1 / 422 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 429 (0.00%)	1 / 423 (0.24%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 429 (0.23%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrub typhus			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 429 (0.00%)	1 / 423 (0.24%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 429 (0.00%)	0 / 423 (0.00%)	0 / 422 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Solifenacin 5 mg	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 423 (0.71%)	12 / 853 (1.41%)	19 / 848 (2.24%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	1 / 423 (0.24%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	2 / 848 (0.24%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Renal stone removal			

subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Apnoea			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiccups			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			

subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			

subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Grand mal convulsion			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Otorrhoea			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 423 (0.24%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 423 (0.24%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatitis toxic			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Rotator cuff syndrome			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	1 / 848 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrub typhus			
subjects affected / exposed	1 / 423 (0.24%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 423 (0.00%)	0 / 853 (0.00%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Intervertebral disc protrusion			

subjects affected / exposed	0 / 423 (0.00%)	1 / 853 (0.12%)	0 / 848 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	Mirabegron 25 mg	Mirabegron 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 429 (1.86%)	17 / 423 (4.02%)	14 / 422 (3.32%)
Gastrointestinal disorders			
Dry mouth			
subjects affected / exposed	8 / 429 (1.86%)	17 / 423 (4.02%)	14 / 422 (3.32%)
occurrences (all)	8	18	14

Non-serious adverse events	Solifenacin 5 mg	Solifenacin 5 mg + mirabegron 25 mg	Solifenacin 5 mg + mirabegron 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 423 (5.91%)	72 / 853 (8.44%)	60 / 848 (7.08%)
Gastrointestinal disorders			
Dry mouth			
subjects affected / exposed	25 / 423 (5.91%)	72 / 853 (8.44%)	60 / 848 (7.08%)
occurrences (all)	27	73	61

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 September 2013	Substantial amendment 1, dated 09 Sep 2013, is summarized as follows: • Inclusion criterion 3 relating to female patients of childbearing potential and inclusion criterion 14 relating to the number of urgency episodes/24 h, respectively, were clarified. • The sample size justification for change from baseline in mean number of incontinence episodes/24 h was modified to accommodate the 7-day diary period. • The efficacy analyses were modified. The adjustment for multiplicity was changed from a hierarchical testing procedure to a sequential Bonferroni-based testing procedure to control the type 1 error across the variables. Additional sensitivity analyses for the coprimary and key secondary efficacy endpoints were added. • Expected adverse drug reactions (ADRs) and expected risks were updated in line with the company core data sheets. • Antidepressant drugs with anticholinergic ADRs were moved from the list of restricted medications to prohibited medications as these drugs sometimes are used to treat OAB. • Nonsubstantial changes were implemented in addition to the substantial changes mentioned above.
12 November 2014	Substantial amendment 2, dated 12 Nov 2014, is summarized as follows. • The number of screened patients was increased to meet the target of 3392 randomized patients. • The number of patients to be randomized in the ABPM substudy was increased to ensure the number of 608 evaluable patients. In addition, the investigator was allowed to repeat the baseline (directly) and week 4 (at week 8) ABPM assessments to increase the number of evaluable patients in the ABPM substudy. • Exclusion criteria 4, 10 and 24 relating to neurological cause for detrusor overactivity, QTcF interval (QT interval corrected using Fridericia's correction formula) and urinary tract infection (UTI), respectively, were clarified. • The list of prohibited or restricted medications was removed from Appendix 1 of the protocol and was provided to investigational sites via separate communications.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to lack of data integrity, one site's data was not included in the efficacy and safety analysis.

Notes: