



Clinical trial results:

A Phase IIb Randomized, Placebo- and Active Comparator (Tolterodine)-Controlled, 2-Part Clinical Study of the Efficacy and Safety of MK-4618 in Patients with Overactive Bladder

A 52-week Extension to: A Phase IIb Randomized, Placebo- and Active Comparator (Tolterodine)-Controlled, 2-Part Clinical Study of the Efficacy and Safety of MK-4618 in Patients with Overactive Bladder

Summary

EudraCT number	2010-022121-15
Trial protocol	SE DE GB DK AT NO PL IT
Global end of trial date	10 October 2013

Results information

Result version number	v2 (current)
This version publication date	15 July 2016
First version publication date	19 April 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	4618-008
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01314872
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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	10 October 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 October 2012
Global end of trial reached?	Yes
Global end of trial date	10 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

(1.) To investigate a dose-related reduction in average number of daily micturitions of vibegron compared with placebo at Week 8 in participants with Overactive Bladder (OAB). (2.) To assess the safety and tolerability of treatment with the selected vibegron (MK-4618) doses either alone or dosed concomitantly with tolterodine ER.

The primary hypothesis of the base study is that administration of vibegron demonstrates a dose-related reduction, compared with placebo, in average number of daily micturitions in participants with OAB after 8 weeks of treatment.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 March 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Norway: 75
Country: Number of subjects enrolled	Poland: 38
Country: Number of subjects enrolled	Sweden: 47
Country: Number of subjects enrolled	United Kingdom: 67
Country: Number of subjects enrolled	Austria: 9
Country: Number of subjects enrolled	Denmark: 47
Country: Number of subjects enrolled	Germany: 104
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	United States: 525
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Canada: 20
Country: Number of subjects enrolled	Japan: 288
Country: Number of subjects enrolled	Korea, Republic of: 38

Country: Number of subjects enrolled	Mexico: 3
Country: Number of subjects enrolled	New Zealand: 20
Country: Number of subjects enrolled	Peru: 35
Country: Number of subjects enrolled	Puerto Rico: 5
Country: Number of subjects enrolled	Russian Federation: 15
Country: Number of subjects enrolled	South Africa: 54
Worldwide total number of subjects	1395
EEA total number of subjects	391

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)	982
From 65 to 84 years	413
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This was a 2-Part, randomized, double blind placebo- and active-controlled, parallel-group study of vibegron in men and women with OAB. Participants enrolled in Part 1 were not eligible to participate in Part 2. Participants who completed Part 1 or Part 2 were eligible to enroll in an optional 1-year safety extension.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: placebo

Arm description:

Participants received two placebo matching vibegron tablets and one placebo matching tolterodine extended release (ER) capsule, taken orally each morning, for 8 weeks.

Arm type	Placebo
Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received placebo matching vibegron tablets, taken orally each morning.

Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received a placebo matching tolterodine ER capsule, taken orally each morning.

Arm title	Part 1: vibegron 3 mg
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Arm description:

Participants received one vibegron 3 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	MK-4618
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg depending on their vibegron Arm assignment, taken orally each morning.

Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Other use
Dosage and administration details:	
Participants received a placebo matching tolterodine ER capsule, taken orally each morning.	
Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received placebo matching vibegron tablets, taken orally each morning.	
Arm title	Part 1: vibegron 15 mg
Arm description:	
Participants received one vibegron 15 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	MK-4618
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg depending on their vibegron Arm assignment, taken orally each morning.	
Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Participants received a placebo matching tolterodine ER capsule, taken orally each morning.	
Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received placebo matching vibegron tablets, taken orally each morning.	
Arm title	Part 1: vibegron 50 mg
Arm description:	
Participants received one vibegron 50 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Arm type	Experimental
Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	4618
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg depending on their vibegron Arm assignment, taken orally each morning.

Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Participants received placebo matching vibegron tablets, taken orally each morning.

Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:
Participants received a placebo matching tolterodine ER capsule, taken orally each morning.

Arm title	Part 1: vibegron 100 mg
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Arm description:
Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.

Arm type	Active comparator
Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	MK-4618
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg depending on their vibegron Arm assignment, taken orally each morning.

Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:
Participants received a placebo matching tolterodine ER capsule, taken orally each morning.

Arm title	Part 1: tolterodine ER 4 mg
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Arm description:
Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 8 weeks.

Arm type	Active comparator
Investigational medicinal product name	tolterodine ER
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:
Participants received one tolterodine ER 4 mg capsule, taken orally once a day.

Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received placebo matching vibegron tablets, taken orally each morning.

Arm title	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg
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Arm description:

Participants received one vibegron 50 mg tablet and one placebo matching vibegron tablet, taken orally each morning, for 8 weeks. They also received one tolterodine ER 4 mg capsule for the first 4 weeks and one placebo matching tolterodine ER capsule for the second 4 weeks, both taken orally each morning.

Arm type	Experimental
Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	MK-4618
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg depending on their vibegron Arm assignment, taken orally each morning.

Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

participants received placebo matching vibegron tablets, taken orally each morning.

Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received a placebo matching tolterodine ER capsule, taken orally each morning.

Investigational medicinal product name	tolterodine ER
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received one tolterodine ER 4 mg capsule, taken orally each morning.

Arm title	Part 2: placebo
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Arm description:

Participants received two placebo matching vibegron tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 4 weeks.

Arm type	Placebo
Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received a placebo matching tolterodine ER capsule, taken orally each morning.

Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received placebo matching vibegron tablets, taken orally each morning.	
Arm title	Part 2: vibegron 100 mg
Arm description:	
Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 4 weeks.	
Arm type	Experimental
Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Participants received a placebo matching tolterodine ER capsule, taken orally each morning.	
Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	MK-4618
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg depending on their vibegron Arm assignment, taken orally each morning.	
Arm title	Part 2: tolterodine ER 4 mg
Arm description:	
Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 4 weeks.	
Arm type	Active comparator
Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received placebo matching vibegron tablets, taken orally each morning.	
Investigational medicinal product name	tolterodine ER
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Participants received one tolterodine ER 4 mg capsule, taken orally once a day.	
Arm title	Part 2: vibegron 100 mg + tolterodine ER 4 mg
Arm description:	
Participants received two vibegron 50 mg tablets and one tolterodine ER 4 mg capsule, taken orally each morning, for 4 weeks.	
Arm type	Experimental

Investigational medicinal product name	tolterodine ER
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received one tolterodine ER 4 mg capsule, taken orally once a day.

Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	MK-4618
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg depending on their vibegron Arm assignment, taken orally each morning.

Number of subjects in period 1	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg
Started	141	144	134
Completed	131	138	128
Not completed	10	6	6
Consent withdrawn by subject	3	1	-
Physician decision	-	1	-
Adverse event, non-fatal	4	2	3
Lost to follow-up	-	1	2
Lack of efficacy	1	-	-
Protocol deviation	2	1	1

Number of subjects in period 1	Part 1: vibegron 50 mg	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg
Started	150	149	135
Completed	143	142	128
Not completed	7	7	7
Consent withdrawn by subject	2	3	1
Physician decision	1	-	-
Adverse event, non-fatal	2	2	4
Lost to follow-up	2	1	1
Lack of efficacy	-	-	1
Protocol deviation	-	1	-

Number of subjects in period 1	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	Part 2: placebo	Part 2: vibegron 100 mg
Started	134	64	112
Completed	126	57	106
Not completed	8	7	6

Consent withdrawn by subject	3	2	2
Physician decision	-	-	-
Adverse event, non-fatal	4	2	3
Lost to follow-up	1	1	1
Lack of efficacy	-	2	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part 2: tolterodine ER 4 mg	Part 2: vibegron 100 mg + tolterodine ER 4 mg
Started	122	110
Completed	118	107
Not completed	4	3
Consent withdrawn by subject	2	1
Physician decision	1	-
Adverse event, non-fatal	-	1
Lost to follow-up	-	-
Lack of efficacy	-	-
Protocol deviation	1	1

Period 2

Period 2 title	Extension Study
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Extension Study: vibegron 50 mg

Arm description:

Participants in Base Study/Part 1 who received vibegron 50 mg continued their treatment in the Extension Study. In addition, participants in Base Study/Part 1 who received vibegron 3 mg received vibegron 50 mg in the Extension Study. Also, participants in Base Study/Part 1 who received vibegron 50 mg + tolterodine ER for 4 weeks, followed by vibegron 50 mg alone for 4 weeks, remained on vibegron 50 mg in the Extension Study. In the extension, participants received one vibegron 50 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 52 weeks.

Arm type	Experimental
Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants were randomized to receive vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg, taken orally each morning.

Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received a placebo matching tolterodine ER capsule, taken orally each morning.

Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received placebo matching vibegron tablets, taken orally each morning.

Arm title	Extension Study: vibegron 100 mg
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Arm description:

Participants in Base Study/Part 1 or Part 2 who received vibegron 100 mg continued their treatment in the Extension Study. In addition, participants in Base Study/Part 1 who received vibegron 15 mg received vibegron 100 mg in the Extension Study. In the extension, participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 52 weeks.

Arm type	Experimental
Investigational medicinal product name	placebo matching tolterodine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received a placebo matching tolterodine ER capsule, taken orally each morning.

Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg, taken orally each morning.

Arm title	Extension Study: tolterodine ER 4 mg
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Arm description:

Participants in Base Study/Part 1 or Part 2 who received tolterodine ER 4 mg continued their treatment in the Extension Study. In addition, participants in Base Study/Part 1 who received placebo also received tolterodine ER 4 mg in the Extension Study. In the extension, participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 52 weeks.

Arm type	Active comparator
Investigational medicinal product name	placebo matching vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received placebo matching vibegron tablets, taken orally each morning.

Investigational medicinal product name	tolterodine ER
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Participants received one tolterodine ER 4 mg capsule, taken orally each morning.	
Arm title	Extension Study: vibegron 100 mg + tolterodine ER 4 mg

Arm description:

Participants in Base Study/Part 1 who received vibegron 100 mg + tolterodine ER 4 mg continued their treatment in the Extension Study. In addition, participants in Base Study/Part 2 who received placebo were assigned to the vibegron 100 mg + tolterodine ER 4 mg arm in the Extension Study. In the extension, participants received two vibegron 50 mg tablets and one tolterodine ER 4 mg capsule, taken orally each morning, for 52 weeks.

Arm type	Experimental
Investigational medicinal product name	tolterodine ER
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received one tolterodine ER 4 mg capsule, taken orally once a day.

Investigational medicinal product name	vibegron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received vibegron tablets at dosages of 3 mg, 15 mg, 50 mg, or 100 mg, taken orally each morning.

Number of subjects in period 2^[1]	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg	Extension Study: tolterodine ER 4 mg
Started	223	248	240
Completed	175	188	187
Not completed	48	60	53
Consent withdrawn by subject	14	17	12
Adverse event, non-fatal	13	16	24
Pregnancy	-	-	-
Non-compliance with study drug	3	3	1
Study terminated by sponsor	2	2	3
Lost to follow-up	6	7	2
Lack of efficacy	7	12	9
Protocol deviation	3	3	2

Number of subjects in period 2^[1]	Extension Study: vibegron 100 mg +
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	tolterodine ER 4 mg
Started	134
Completed	110
Not completed	24
Consent withdrawn by subject	4
Adverse event, non-fatal	9
Pregnancy	1
Non-compliance with study drug	2
Study terminated by sponsor	-
Lost to follow-up	6
Lack of efficacy	2
Protocol deviation	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants who completed Part 1 or Part 2 of the Base Study were eligible to enroll in an optional 1-year safety extension.

Baseline characteristics

Reporting groups	
Reporting group title	Part 1: placebo
Reporting group description: Participants received two placebo matching vibegron tablets and one placebo matching tolterodine extended release (ER) capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 3 mg
Reporting group description: Participants received one vibegron 3 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 15 mg
Reporting group description: Participants received one vibegron 15 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 50 mg
Reporting group description: Participants received one vibegron 50 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 100 mg
Reporting group description: Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: tolterodine ER 4 mg
Reporting group description: Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg
Reporting group description: Participants received one vibegron 50 mg tablet and one placebo matching vibegron tablet, taken orally each morning, for 8 weeks. They also received one tolterodine ER 4 mg capsule for the first 4 weeks and one placebo matching tolterodine ER capsule for the second 4 weeks, both taken orally each morning.	
Reporting group title	Part 2: placebo
Reporting group description: Participants received two placebo matching vibegron tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 4 weeks.	
Reporting group title	Part 2: vibegron 100 mg
Reporting group description: Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 4 weeks.	
Reporting group title	Part 2: tolterodine ER 4 mg
Reporting group description: Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 4 weeks.	
Reporting group title	Part 2: vibegron 100 mg + tolterodine ER 4 mg
Reporting group description: Participants received two vibegron 50 mg tablets and one tolterodine ER 4 mg capsule, taken orally each morning, for 4 weeks.	

Reporting group values	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg
Number of subjects	141	144	134

Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	58.6 ± 9	59.4 ± 8.7	58.6 ± 8.1
Gender categorical Units: Subjects			
Female	128	131	125
Male	13	13	9

Reporting group values	Part 1: vibegron 50 mg	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg
Number of subjects	150	149	135
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	60.3 ± 8.7	60.3 ± 8.3	59.1 ± 8.1
Gender categorical Units: Subjects			
Female	129	135	121
Male	21	14	14

Reporting group values	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	Part 2: placebo	Part 2: vibegron 100 mg
Number of subjects	134	64	112
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	59.4 ± 8.5	56.3 ± 10.6	57.2 ± 10.1
Gender categorical Units: Subjects			
Female	119	57	101
Male	15	7	11

Reporting group values	Part 2: tolterodine ER 4 mg	Part 2: vibegron 100 mg + tolterodine ER 4 mg	Total
Number of subjects	122	110	1395
Age categorical Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	57.9	55.5	
standard deviation	± 10.9	± 11.7	-
Gender categorical			
Units: Subjects			
Female	110	95	1251
Male	12	15	144

End points

End points reporting groups

Reporting group title	Part 1: placebo
Reporting group description: Participants received two placebo matching vibegron tablets and one placebo matching tolterodine extended release (ER) capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 3 mg
Reporting group description: Participants received one vibegron 3 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 15 mg
Reporting group description: Participants received one vibegron 15 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 50 mg
Reporting group description: Participants received one vibegron 50 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 100 mg
Reporting group description: Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: tolterodine ER 4 mg
Reporting group description: Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 8 weeks.	
Reporting group title	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg
Reporting group description: Participants received one vibegron 50 mg tablet and one placebo matching vibegron tablet, taken orally each morning, for 8 weeks. They also received one tolterodine ER 4 mg capsule for the first 4 weeks and one placebo matching tolterodine ER capsule for the second 4 weeks, both taken orally each morning.	
Reporting group title	Part 2: placebo
Reporting group description: Participants received two placebo matching vibegron tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 4 weeks.	
Reporting group title	Part 2: vibegron 100 mg
Reporting group description: Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 4 weeks.	
Reporting group title	Part 2: tolterodine ER 4 mg
Reporting group description: Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 4 weeks.	
Reporting group title	Part 2: vibegron 100 mg + tolterodine ER 4 mg
Reporting group description: Participants received two vibegron 50 mg tablets and one tolterodine ER 4 mg capsule, taken orally each morning, for 4 weeks.	
Reporting group title	Extension Study: vibegron 50 mg
Reporting group description: Participants in Base Study/Part 1 who received vibegron 50 mg continued their treatment in the Extension Study. In addition, participants in Base Study/Part 1 who received vibegron 3 mg received vibegron 50 mg in the Extension Study. Also, participants in Base Study/Part 1 who received vibegron 50 mg + tolterodine ER for 4 weeks, followed by vibegron 50 mg alone for 4 weeks, remained on vibegron 50 mg in the Extension Study. In the extension, participants received one vibegron 50 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken	

orally each morning, for 52 weeks.

Reporting group title	Extension Study: vibegron 100 mg
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Reporting group description:

Participants in Base Study/Part 1 or Part 2 who received vibegron 100 mg continued their treatment in the Extension Study. In addition, participants in Base Study/Part 1 who received vibegron 15 mg received vibegron 100 mg in the Extension Study. In the extension, participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 52 weeks.

Reporting group title	Extension Study: tolterodine ER 4 mg
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Reporting group description:

Participants in Base Study/Part 1 or Part 2 who received tolterodine ER 4 mg continued their treatment in the Extension Study. In addition, participants in Base Study/Part 1 who received placebo also received tolterodine ER 4 mg in the Extension Study. In the extension, participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 52 weeks.

Reporting group title	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
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Reporting group description:

Participants in Base Study/Part 1 who received vibegron 100 mg + tolterodine ER 4 mg continued their treatment in the Extension Study. In addition, participants in Base Study/Part 2 who received placebo were assigned to the vibegron 100 mg + tolterodine ER 4 mg arm in the Extension Study. In the extension, participants received two vibegron 50 mg tablets and one tolterodine ER 4 mg capsule, taken orally each morning, for 52 weeks.

Primary: Base Study/Part 1: Change from Baseline in Average Daily Number of Micturitions at Week 8

End point title	Base Study/Part 1: Change from Baseline in Average Daily Number of Micturitions at Week 8 ^[1]
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End point description:

Participants were required to keep a voiding diary, recording the occurrence of each micturition. The average daily number of micturitions was calculated as the total number of micturitions that occurred over a week (4 to 10 days) during the Base Study, divided by the total number of days of voiding kept in the participant's diary. Baseline was defined as the average daily number of daily micturitions that occurred during the week of placebo run-in prior to Week 0 visit. This endpoint was based on the full analysis set population, which included all randomized participants who received at least one dose of study treatment and have either baseline data or at least one post-randomization observation for the analysis endpoint.

End point type	Primary
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End point timeframe:

Baseline and Week 8

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Participants in this treatment group took MK-4618 50 mg + tolterodine ER 4 mg for the first 4 weeks and MK-4618 50 mg in the later 4 weeks. This treatment group was not statistically analyzed.

End point values	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg	Part 1: vibegron 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	141	144	132	148
Units: Average Daily Number of Micturitions				
least squares mean (confidence interval 95%)	-1.16 (-1.5 to -0.82)	-1.62 (-1.95 to -1.29)	-1.61 (-1.96 to -1.27)	-1.8 (-2.13 to -1.47)

End point values	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	148	134	134	
Units: Average Daily Number of Micturitions				
least squares mean (confidence interval 95%)	-2.07 (-2.4 to -1.74)	-1.71 (-2.05 to -1.36)	-2.05 (-2.4 to -1.7)	

Statistical analyses

Statistical analysis title	Difference in Least Squares (LS) Means
Statistical analysis description:	
Difference in LS Means: vibegron 3 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 3 mg
Number of subjects included in analysis	285
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.056
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS means
Point estimate	-0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.92
upper limit	0.01

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 15 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 15 mg
Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.064
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.93
upper limit	0.03

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 50 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 50 mg
Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.11
upper limit	-0.18

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 100 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 100 mg
Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.37
upper limit	-0.44

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: tolterodine ER 4 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: tolterodine ER 4 mg

Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.026
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.02
upper limit	-0.07

Primary: Base Study/Part 1 + Part 2: Number of Participants Who Experienced an Adverse Event (AE)

End point title	Base Study/Part 1 + Part 2: Number of Participants Who Experienced an Adverse Event (AE) ^[2]
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End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug, whether or not it is considered related to the study drug. This endpoint was based on the all participants as treated population, which consisted of all randomized participants who received at least one dose of study treatment. Participants were included in the treatment group corresponding to the study treatment they actually received.

End point type	Primary
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End point timeframe:

Part 1: up to 8 weeks; Part 2: up to 4 weeks. The time frame was an additional 2 weeks for participants not continuing to the Extension Study.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was conducted for Base Study/Part 1 + Part 2: Number of Participants Who Experienced an Adverse Event (AE).

End point values	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg	Part 1: vibegron 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	141	144	134	148
Units: Participants	66	55	70	62

End point values	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	Part 2: placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	149	135	134	64
Units: Participants	70	68	69	22

End point values	Part 2: vibegron 100 mg	Part 2: tolterodine ER 4 mg	Part 2: vibegron 100 mg + tolterodine ER 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	112	122	110	
Units: Participants	37	48	40	

Statistical analyses

No statistical analyses for this end point

Primary: Base Study/Part 1 + Part 2: Number of Participants Who Had Study Medication Withdrawn Due to an AE

End point title	Base Study/Part 1 + Part 2: Number of Participants Who Had Study Medication Withdrawn Due to an AE ^[3]
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End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug, whether or not it is considered related to the study drug. This endpoint was based on the all participants as treated population, which consisted of all randomized participants who received at least one dose of study treatment. Participants were included in the treatment group corresponding to the study treatment they actually received.

End point type	Primary
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End point timeframe:

Part 1: up to 8 weeks; Part 2: up to 4 weeks

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was conducted for Base Study/Part 1 + Part 2: Number of Participants Who Had Study Medication Withdrawn Due to an AE.

End point values	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg	Part 1: vibegron 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	141	144	134	148
Units: Participants	3	3	4	2

End point values	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	Part 2: placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	149	135	134	64
Units: Participants	2	4	3	2

End point values	Part 2: vibegron 100 mg	Part 2: tolterodine ER 4 mg	Part 2: vibegron 100 mg + tolterodine ER 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	112	122	110	
Units: Participants	4	0	2	

Statistical analyses

No statistical analyses for this end point

Primary: Extension Study: Number of Participants Who Experienced an AE

End point title	Extension Study: Number of Participants Who Experienced an AE ^[4]
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End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug, whether or not it is considered related to the study drug. This endpoint was based on the all participants as treated population, which consisted of all randomized participants who received at least one dose of study treatment. Participants were included in the treatment group corresponding to the study treatment they actually received.

End point type	Primary
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End point timeframe:

Up to Week 54 of the Extension Study

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was conducted for Extension Study: Number of Participants Who Experienced an AE.

End point values	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg	Extension Study: tolterodine ER 4 mg	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	223	248	240	134
Units: Participants	134	157	158	82

Statistical analyses

No statistical analyses for this end point

Primary: Extension Study: Number of Participants Who Had Study Medication Withdrawn Due to an AE

End point title	Extension Study: Number of Participants Who Had Study
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End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug, whether or not it is considered related to the study drug. This endpoint was based on the all participants as treated population, which consisted of all randomized participants who received at least one dose of study treatment. Participants were included in the treatment group corresponding to the study treatment they actually received.

End point type

Primary

End point timeframe:

Up to Week 52 of the Extension Study

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was conducted for Extension Study: Number of Participants Who Had Study Medication Withdrawn Due to an AE.

End point values	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg	Extension Study: tolterodine ER 4 mg	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	223	248	240	134
Units: Participants	11	14	24	7

Statistical analyses

No statistical analyses for this end point

Secondary: Base Study/Part 1: Change from Baseline in Average Daily Number of Urge Incontinence Episodes at Week 8

End point title

Base Study/Part 1: Change from Baseline in Average Daily Number of Urge Incontinence Episodes at Week 8^[6]

End point description:

Participants were required to keep a voiding diary, recording the occurrence of each urge incontinence episode. The average daily number of urge incontinence episodes was calculated as the total number of times a participant experienced such an episode over a week (4 to 10 days) during the Base Study, divided by the total number of days of voiding kept in the participant's diary. This endpoint was based on the full analysis set population, which included all randomized participants who received at least one dose of study treatment and have either baseline data or at least one post-randomization observation for the analysis endpoint. This outcome measure included OAB Wet (OAB with urinary urgency incontinence) participants only. Baseline was defined as the average daily number of urge incontinence episodes that occurred during the week of placebo run-in prior to Week 0 visit.

End point type

Secondary

End point timeframe:

Baseline and Week 8

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Participants in this treatment group took MK-4618 50 mg + tolterodine ER 4 mg for the first 4 weeks and MK-4618 50 mg in the later 4 weeks. This treatment group was not statistically analyzed.

End point values	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg	Part 1: vibegron 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	118	113	111	121
Units: Number of Urge Incontinence Episodes				
least squares mean (confidence interval 95%)	-1.24 (-1.52 to -0.95)	-1.52 (-1.81 to -1.23)	-1.81 (-2.1 to 1.51)	-1.95 (-2.23 to -1.67)

End point values	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	122	100	111	
Units: Number of Urge Incontinence Episodes				
least squares mean (confidence interval 95%)	-1.95 (-2.23 to -1.67)	-1.69 (-2 to -1.38)	-1.71 (-2.01 to -1.42)	

Statistical analyses

Statistical analysis title	Difference in LS Means
Statistical analysis description: Difference in LS Means: vibegron 3 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 3 mg
Number of subjects included in analysis	231
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.167
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.68
upper limit	0.12

Statistical analysis title	Difference in LS Means
Statistical analysis description: Difference in LS Means: vibegron 15 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 15 mg

Number of subjects included in analysis	229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.97
upper limit	-0.17

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 50 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 50 mg
Number of subjects included in analysis	239
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.11
upper limit	-0.33

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 100 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 100 mg
Number of subjects included in analysis	240
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	-0.32

Statistical analysis title	Difference in LS Means
Statistical analysis description: Difference in LS Means: tolterodine ER 4 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: tolterodine ER 4 mg
Number of subjects included in analysis	218
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.03
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.87
upper limit	-0.04

Secondary: Base Study/Part 1: Change from Baseline in Average Daily Number of Total Incontinence Episodes at Week 8

End point title	Base Study/Part 1: Change from Baseline in Average Daily Number of Total Incontinence Episodes at Week 8 ^[7]
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End point description:

Participants were required to keep a voiding diary, recording the occurrence of each total incontinence episode. The average daily number of total incontinence episodes was calculated as the total number of times a participant experienced such an episode over a week (4 to 10 days) during the Base Study, divided by the total number of days of voiding kept in the participant's diary. This endpoint was based on the full analysis set population, which included all randomized participants who received at least one dose of study treatment and have either baseline data or at least one post-randomization observation for the analysis endpoint. This outcome measure included OAB Wet participants only. Baseline was defined as the average daily number of total incontinence episodes that occurred during the week of placebo run-in prior to Week 0 visit.

End point type	Secondary
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End point timeframe:

Baseline and Week 8

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Participants in this treatment group took MK-4618 50 mg + tolterodine ER 4 mg for the first 4 weeks and MK-4618 50 mg in the later 4 weeks. This treatment group was not statistically analyzed.

End point values	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg	Part 1: vibegron 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	118	113	111	121
Units: Incontinence Episodes				
least squares mean (confidence interval 95%)	-1.52 (-1.84 to -1.21)	-1.71 (-2.02 to -1.39)	-2.01 (-2.33 to -1.69)	-2.13 (-2.43 to -1.82)

End point values	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	122	100	111	
Units: Incontinence Episodes				
least squares mean (confidence interval 95%)	-2.11 (-2.41 to -1.8)	-1.86 (-2.2 to -1.52)	-2 (-2.32 to -1.68)	

Statistical analyses

Statistical analysis title	Difference in LS Means
Statistical analysis description: Difference in LS Means: vibegron 3 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 3 mg
Number of subjects included in analysis	231
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.401
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.61
upper limit	0.25

Statistical analysis title	Difference in LS Means
Statistical analysis description: Difference in LS Means: vibegron 15 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 15 mg
Number of subjects included in analysis	229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.029
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.48

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.91
upper limit	-0.05

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 50 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 50 mg
Number of subjects included in analysis	239
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.02
upper limit	-0.18

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 100 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 100 mg
Number of subjects included in analysis	240
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.01
upper limit	-0.16

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: tolterodine ER 4 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: tolterodine ER 4 mg

Number of subjects included in analysis	218
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.14
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.78
upper limit	0.11

Secondary: Base Study/Part 1: Change from Baseline in Average Daily Number of Strong Urge Episodes at Week 8

End point title	Base Study/Part 1: Change from Baseline in Average Daily Number of Strong Urge Episodes at Week 8 ^[8]
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End point description:

Participants were required to keep a voiding diary, recording the occurrence of each strong urge episode. The average daily number of strong urge episodes was calculated as the total number of times a participant experienced such an episode over a week (4 to 10 days) during the Base Study, divided by the total number of days of voiding kept in the participant's diary. Baseline was defined as the average daily number of strong urge episodes that occurred during the week of placebo run-in prior to Week 0 visit. This endpoint was based on the full analysis set population, which included all randomized participants who received at least one dose of study treatment and have either baseline data or at least one post-randomization observation for the analysis endpoint.

End point type	Secondary
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End point timeframe:

Baseline and Week 8

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Participants in this treatment group took MK-4618 50 mg + tolterodine ER 4 mg for the first 4 weeks and MK-4618 50 mg in the later 4 weeks. This treatment group was not statistically analyzed.

End point values	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg	Part 1: vibegron 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	141	144	132	148
Units: Strong Urge Episodes				
least squares mean (confidence interval 95%)	-1.59 (-2.07 to -1.11)	-1.77 (-2.24 to -1.3)	-2.27 (-2.76 to -1.78)	-2.36 (-2.82 to -1.89)

End point values	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	
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Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	148	134	134	
Units: Strong Urge Episodes				
least squares mean (confidence interval 95%)	-2.83 (-3.3 to -2.37)	-2.53 (-3.03 to -2.04)	-2.73 (-3.22 to -2.24)	

Statistical analyses

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 3 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 3 mg
Number of subjects included in analysis	285
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.598
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.84
upper limit	0.49

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 15 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 15 mg
Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.052
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.35
upper limit	0.01

Statistical analysis title	Difference in LS Means
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Statistical analysis description:	
Difference in LS Means: vibegron 50 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 50 mg
Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.024
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.43
upper limit	-0.1

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 100 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: vibegron 100 mg
Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	-0.58

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: tolterodine ER 4 mg vs. placebo at Week 8	
Comparison groups	Part 1: placebo v Part 1: tolterodine ER 4 mg
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.94

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.62
upper limit	-0.26

Secondary: Extension Study: Change From Baseline in Average Daily Number of Micturitions at Week 52

End point title	Extension Study: Change From Baseline in Average Daily Number of Micturitions at Week 52
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End point description:

Participants were required to keep a voiding diary, recording the daily occurrence of each micturition. The average daily number of micturitions was calculated as the total number of recorded micturitions that occurred during the 52-week Extension Study, divided by the total number of days of voiding kept in the participant's diary. Baseline was defined as the value at Week 0 of the Base Study. This endpoint was based on the full analysis set population, which included all randomized participants who received at least one dose of study treatment and have either baseline data or at least one post-randomization observation for the analysis endpoint.

End point type	Secondary
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End point timeframe:

Baseline and Week 52 of Extension Study

End point values	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg	Extension Study: tolterodine ER 4 mg	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	223	246	240	134
Units: Average Daily Number of Micturitions				
least squares mean (confidence interval 95%)	-2.53 (-2.87 to -2.2)	-2.77 (-3.08 to -2.45)	-2.15 (-2.47 to -1.83)	-3.25 (-3.67 to -2.83)

Statistical analyses

Statistical analysis title	Difference in LS Means
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Statistical analysis description:

Difference in LS Means: vibegron 100 mg + tolterodine ER 4 mg vs. vibegron 100 mg at Week 52

Comparison groups	Extension Study: vibegron 100 mg v Extension Study: vibegron 100 mg + tolterodine ER 4 mg
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Number of subjects included in analysis	380
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in LS Means
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0.03

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 100 mg + tolterodine ER 4 mg vs. tolterodine ER 4 mg at Week 52	
Comparison groups	Extension Study: tolterodine ER 4 mg v Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in LS Means
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.62
upper limit	-0.58

Secondary: Extension Study: Change from Baseline in Average Daily Number of Urge Incontinence Episodes at Week 52

End point title	Extension Study: Change from Baseline in Average Daily Number of Urge Incontinence Episodes at Week 52
End point description:	
<p>Participants were required to keep a voiding diary, recording the occurrence of each urge incontinence episode. The average daily number of urge incontinence episodes was calculated as the total number of times a participant experienced such an episode during 52-week Extension Study, divided by the total number of days of voiding kept in the participant's diary. This endpoint was based on the full analysis set population, which included all randomized participants who received at least one dose of study treatment and have either baseline data or at least one post-randomization observation for the analysis endpoint. This outcome measure included OAB Wet participants only. Baseline was defined as the value at Week 0 of the Base Study.</p>	
End point type	Secondary
End point timeframe:	
Baseline and Week 52 of Extension Study	

End point values	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg	Extension Study: tolterodine ER 4 mg	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	179	200	189	112
Units: Avg Daily No of Urge Incontinence Eps				
least squares mean (confidence interval 95%)	-2.43 (-2.72 to -2.14)	-2.15 (-2.43 to -1.87)	-2.23 (-2.51 to -1.94)	-2.44 (-2.79 to -2.09)

Statistical analyses

Statistical analysis title	Difference in LS Means
Statistical analysis description:	
Difference in LS Means: vibegron 100 mg + tolterodine ER 4 mg vs. vibegron 100 mg at Week 52	
Comparison groups	Extension Study: vibegron 100 mg v Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in LS Means
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.71
upper limit	0.13

Statistical analysis title	Difference in LS Means
Comparison groups	Extension Study: vibegron 100 mg + tolterodine ER 4 mg v Extension Study: tolterodine ER 4 mg
Number of subjects included in analysis	301
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in LS Means
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.64
upper limit	0.21

Secondary: Extension Study: Change from Baseline in Average Daily Number of Total Incontinence Episodes at Week 52

End point title	Extension Study: Change from Baseline in Average Daily Number of Total Incontinence Episodes at Week 52
End point description:	
Participants were required to keep a voiding diary, recording the occurrence of each total incontinence episode. The average daily number of total incontinence episodes was calculated as the total number of times a participant experienced such an episode during 52-week Extension Study, divided by the total number of days of voiding kept in the participant's diary. This endpoint was based on the full analysis set population, which included all randomized participants who received at least one dose of study treatment and have either baseline data or at least one post-randomization observation for the analysis endpoint. This outcome measure included OAB Wet participants only. Baseline was defined as the value at Week 0 of the Base Study.	
End point type	Secondary
End point timeframe:	
Baseline and Week 52 of Extension Study	

End point values	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg	Extension Study: tolterodine ER 4 mg	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	179	200	189	112
Units: Avg Daily No of Total Incontinence Eps				
least squares mean (confidence interval 95%)	-2.7 (-3.03 to -2.36)	-2.42 (-2.74 to -2.09)	-2.5 (-2.83 to -2.17)	-2.48 (-2.89 to -2.07)

Statistical analyses

Statistical analysis title	Difference in LS Means
Comparison groups	Extension Study: vibegron 100 mg + tolterodine ER 4 mg v Extension Study: tolterodine ER 4 mg
Number of subjects included in analysis	301
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in LS Means
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	0.51

Statistical analysis title	Difference in LS Means
Comparison groups	Extension Study: vibegron 100 mg + tolterodine ER 4 mg v Extension Study: vibegron 100 mg

Number of subjects included in analysis	312
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in LS Means
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.56
upper limit	0.43

Secondary: Extension Study: Change From Baseline in Average Daily Number of Strong Urge Episodes at Week 52

End point title	Extension Study: Change From Baseline in Average Daily Number of Strong Urge Episodes at Week 52
End point description:	
Participants were required to keep a voiding diary, recording the occurrence of each strong urge episode. The average daily number of strong urge episodes was calculated as the total number of times a participant experienced such an episode during 52-week Extension Study, divided by the total number of days of voiding kept in the participant's diary. Baseline was defined as the value at Week 0 of the Base Study. This endpoint was based on the full analysis set population, which included all randomized participants who received at least one dose of study treatment and have either baseline data or at least one post-randomization observation for the analysis endpoint.	
End point type	Secondary
End point timeframe:	
Baseline and Week 52 of Extension Study	

End point values	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg	Extension Study: tolterodine ER 4 mg	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	223	246	240	134
Units: Avg Daily Number of Strong Urge Episodes				
least squares mean (confidence interval 95%)	-3.11 (-3.55 to -2.67)	-3.42 (-3.84 to -3)	-2.94 (-3.36 to -2.52)	-4.18 (-4.74 to -3.63)

Statistical analyses

Statistical analysis title	Difference in LS Means
Comparison groups	Extension Study: vibegron 100 mg + tolterodine ER 4 mg v Extension Study: vibegron 100 mg

Number of subjects included in analysis	380
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in LS Means
Point estimate	-0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.45
upper limit	-0.08

Statistical analysis title	Difference in LS Means
Comparison groups	Extension Study: vibegron 100 mg + tolterodine ER 4 mg v Extension Study: tolterodine ER 4 mg
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in LS Means
Point estimate	-1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.93
upper limit	-0.56

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Base Study/Part 1: up to 8 weeks; Base Study/Part 2: up to 4 weeks (time frame was additional 2 weeks for Parts 1 and 2 participants not continuing to Extension Study); Extension Study: up to 54 weeks (including 2 week follow-up).

Adverse event reporting additional description:

All participants as treated population consisted of all randomized participants who received at least one dose of study treatment. Participants were included in treatment group corresponding to study treatment they actually received. Two randomized participants who were not treated were excluded from Part 1: vibegron 50 mg arm.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	Part 1: placebo
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Reporting group description:

Participants received two placebo matching vibegron tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.

Reporting group title	Part 1: vibegron 3 mg
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Reporting group description:

Participants received one vibegron 3 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.

Reporting group title	Part 1: vibegron 15 mg
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Reporting group description:

Participants received one vibegron 15 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.

Reporting group title	Part 1: vibegron 50 mg
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Reporting group description:

Participants received one vibegron 50 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.

Reporting group title	Part 1: vibegron 100 mg
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Reporting group description:

Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 8 weeks.

Reporting group title	Part 1: tolterodine ER 4 mg
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Reporting group description:

Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 8 weeks.

Reporting group title	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg
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Reporting group description:

Participants received one vibegron 50 mg tablet and one placebo matching vibegron tablet, taken orally each morning, for 8 weeks. They also received one tolterodine ER 4 mg capsule for the first 4 weeks and one placebo matching tolterodine ER capsule for the second 4 weeks, both taken orally each morning.

Reporting group title	Part 2: placebo
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Reporting group description:

Participants received two placebo matching vibegron tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 4 weeks.

Reporting group title	Part 2: vibegron 100 mg + tolterodine ER 4 mg
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Reporting group description:

Participants received two vibegron 50 mg tablets and one tolterodine ER 4 mg capsule, taken orally each morning, for 4 weeks.

Reporting group title	Part 2: tolterodine ER 4 mg
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Reporting group description:

Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 4 weeks.

Reporting group title	Part 2: vibegron 100 mg
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Reporting group description:

Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 4 weeks.

Reporting group title	Extension Study: tolterodine ER 4 mg
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Reporting group description:

Participants received one tolterodine ER 4 mg capsule and two placebo matching vibegron tablets, taken orally each morning, for 52 weeks.

Reporting group title	Extension Study: vibegron 100 mg
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Reporting group description:

Participants received two vibegron 50 mg tablets and one placebo matching tolterodine ER capsule, taken orally each morning, for 52 weeks.

Reporting group title	Extension Study: vibegron 50 mg
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Reporting group description:

Participants received one vibegron 50 mg tablet, one placebo matching vibegron tablet, and one placebo matching tolterodine ER capsule, taken orally each morning, for 52 weeks.

Reporting group title	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
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Reporting group description:

Participants received two vibegron 50 mg tablets and one tolterodine ER 4 mg capsule, taken orally each morning, for 52 weeks.

Serious adverse events	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 141 (1.42%)	1 / 144 (0.69%)	0 / 134 (0.00%)
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)			
Breast cancer			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 141 (0.00%)	1 / 144 (0.69%)	0 / 134 (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
Ovarian cancer			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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	1 / 141 (0.71%)	0 / 144 (0.00%)	0 / 134 (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
General disorders and administration site conditions			
Device dislocation			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Anaphylactic reaction			
subjects affected / exposed	1 / 141 (0.71%)	0 / 144 (0.00%)	0 / 134 (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			
Vaginal haemorrhage			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Pleural effusion			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Anxiety			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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

Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Contusion			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Femur fracture			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Foot fracture			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Incisional hernia			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Joint dislocation			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Multiple fractures			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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

Multiple injuries			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Muscle rupture			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Overdose			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Wrist fracture			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Atrial fibrillation			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Myocardial infarction			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Dizziness			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Loss of consciousness			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Autoimmune thrombocytopenia			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Abdominal pain lower			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Ileus			

subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Ileus paralytic			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Pancreatitis acute			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Hepatotoxicity			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Back pain			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Foot deformity			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Muscle haemorrhage			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Osteoarthritis			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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

Periarthritis			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Borrelia infection			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Cellulitis			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Tracheobronchitis			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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			
Dehydration			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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
Diabetes mellitus			
subjects affected / exposed	0 / 141 (0.00%)	0 / 144 (0.00%)	0 / 134 (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	Part 1: vibegron 50 mg	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 148 (0.68%)	0 / 149 (0.00%)	1 / 135 (0.74%)
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)			
Breast cancer			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Ovarian cancer			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
General disorders and administration site conditions			
Device dislocation			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			

Vaginal haemorrhage			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 148 (0.68%)	0 / 149 (0.00%)	0 / 135 (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
Pleural effusion			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Anxiety			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Contusion			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Femur fracture			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Foot fracture			

subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Incisional hernia			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Joint dislocation			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Multiple fractures			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Multiple injuries			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Muscle rupture			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Overdose			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Wrist fracture			

subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Atrial fibrillation			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	1 / 135 (0.74%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Dizziness			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Loss of consciousness			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Autoimmune thrombocytopenia			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Abdominal pain lower			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Ileus			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Ileus paralytic			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Pancreatitis acute			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Hepatotoxicity			

subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Back pain			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Foot deformity			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Muscle haemorrhage			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Osteoarthritis			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Periarthritis			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Borrelia infection			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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

Cellulitis			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Tracheobronchitis			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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			
Dehydration			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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
Diabetes mellitus			
subjects affected / exposed	0 / 148 (0.00%)	0 / 149 (0.00%)	0 / 135 (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	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	Part 2: placebo	Part 2: vibegron 100 mg + tolterodine ER 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 134 (0.75%)	0 / 64 (0.00%)	0 / 110 (0.00%)
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)			
Breast cancer			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Lung adenocarcinoma stage IV			

subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Ovarian cancer			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
General disorders and administration site conditions			
Device dislocation			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Vaginal haemorrhage			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Pleural effusion			

subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Anxiety			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Contusion			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Femur fracture			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Foot fracture			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Incisional hernia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Joint dislocation			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Multiple fractures			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Multiple injuries			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Muscle rupture			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Overdose			
subjects affected / exposed	1 / 134 (0.75%)	0 / 64 (0.00%)	0 / 110 (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
Wrist fracture			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Atrial fibrillation			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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

Myocardial infarction			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Dizziness			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Loss of consciousness			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Autoimmune thrombocytopenia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Abdominal pain lower			

subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Ileus			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Ileus paralytic			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Pancreatitis acute			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Hepatotoxicity			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			
Back pain			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Foot deformity			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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

Muscle haemorrhage			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Osteoarthritis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Periarthritis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Borrelia infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Cellulitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Tracheobronchitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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			

Dehydration			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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
Diabetes mellitus			
subjects affected / exposed	0 / 134 (0.00%)	0 / 64 (0.00%)	0 / 110 (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	Part 2: tolterodine ER 4 mg	Part 2: vibegron 100 mg	Extension Study: tolterodine ER 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 122 (1.64%)	0 / 112 (0.00%)	18 / 240 (7.50%)
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)			
Breast cancer			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Ovarian cancer			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
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 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
General disorders and administration site conditions			
Device dislocation			

subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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			
Vaginal haemorrhage			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Pleural effusion			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
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			
Anxiety			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
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			
Ankle fracture			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Femur fracture			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	1 / 122 (0.82%)	0 / 112 (0.00%)	0 / 240 (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
Incisional hernia			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Joint dislocation			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
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 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Multiple injuries			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Muscle rupture			

subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Wrist fracture			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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			
Atrial fibrillation			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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

Dizziness			
subjects affected / exposed	1 / 122 (0.82%)	0 / 112 (0.00%)	0 / 240 (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
Loss of consciousness			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Autoimmune thrombocytopenia			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 122 (0.82%)	0 / 112 (0.00%)	0 / 240 (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
Ileus			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Ileus paralytic			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pancreatitis acute			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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			
Hepatotoxicity			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
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			
Back pain			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Foot deformity			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Muscle haemorrhage			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Osteoarthritis			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
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 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Borrelia infection			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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
Cellulitis			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
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 / 122 (0.00%)	0 / 112 (0.00%)	2 / 240 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	0 / 240 (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			
Dehydration			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 122 (0.00%)	0 / 112 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Extension Study: vibegron 100 mg	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 248 (3.23%)	14 / 223 (6.28%)	1 / 134 (0.75%)
number of deaths (all causes)	0	0	0
number of deaths resulting from	0	0	0

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	1 / 248 (0.40%)	0 / 223 (0.00%)	0 / 134 (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
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Ovarian cancer			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
General disorders and administration site conditions			
Device dislocation			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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			
Vaginal haemorrhage			
subjects affected / exposed	1 / 248 (0.40%)	0 / 223 (0.00%)	0 / 134 (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

Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Pleural effusion			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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			
Anxiety			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Contusion			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Femur fracture			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Foot fracture			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Incisional hernia			

subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Joint dislocation			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Multiple fractures			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Multiple injuries			
subjects affected / exposed	1 / 248 (0.40%)	0 / 223 (0.00%)	0 / 134 (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
Muscle rupture			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Overdose			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Wrist fracture			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Congenital, familial and genetic disorders			
Atrial septal defect			

subjects affected / exposed	1 / 248 (0.40%)	0 / 223 (0.00%)	0 / 134 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Myocardial infarction			
subjects affected / exposed	1 / 248 (0.40%)	0 / 223 (0.00%)	0 / 134 (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
Myocardial ischaemia			
subjects affected / exposed	1 / 248 (0.40%)	0 / 223 (0.00%)	0 / 134 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 248 (0.00%)	2 / 223 (0.90%)	0 / 134 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Loss of consciousness			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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

Autoimmune thrombocytopenia subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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			
Abdominal pain lower subjects affected / exposed	1 / 248 (0.40%)	0 / 223 (0.00%)	0 / 134 (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
Gastroesophageal reflux disease subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Ileus subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Ileus paralytic subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Pancreatitis acute subjects affected / exposed	1 / 248 (0.40%)	0 / 223 (0.00%)	0 / 134 (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			
Hepatotoxicity subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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			
Back pain			

subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Foot deformity			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Muscle haemorrhage			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Osteoarthritis			
subjects affected / exposed	0 / 248 (0.00%)	2 / 223 (0.90%)	0 / 134 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Borrelia infection			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	1 / 134 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Tracheobronchitis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 223 (0.45%)	0 / 134 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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
Diabetes mellitus			
subjects affected / exposed	0 / 248 (0.00%)	0 / 223 (0.00%)	0 / 134 (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

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Part 1: placebo	Part 1: vibegron 3 mg	Part 1: vibegron 15 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 141 (22.70%)	21 / 144 (14.58%)	27 / 134 (20.15%)
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	2 / 141 (1.42%)	3 / 144 (2.08%)	6 / 134 (4.48%)
occurrences (all)	2	3	6
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 141 (4.96%)	3 / 144 (2.08%)	6 / 134 (4.48%)
occurrences (all)	8	3	6
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	3 / 141 (2.13%)	5 / 144 (3.47%)	6 / 134 (4.48%)
occurrences (all)	4	5	6
Dry mouth			

subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2	5 / 144 (3.47%) 5	6 / 134 (4.48%) 6
Diarrhoea subjects affected / exposed occurrences (all)	5 / 141 (3.55%) 6	4 / 144 (2.78%) 4	2 / 134 (1.49%) 2
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	14 / 141 (9.93%) 15	3 / 144 (2.08%) 3	7 / 134 (5.22%) 8
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2	2 / 144 (1.39%) 3	1 / 134 (0.75%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	5 / 141 (3.55%) 5	5 / 144 (3.47%) 5	5 / 134 (3.73%) 5

Non-serious adverse events	Part 1: vibegron 50 mg	Part 1: vibegron 100 mg	Part 1: tolterodine ER 4 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	30 / 148 (20.27%)	33 / 149 (22.15%)	33 / 135 (24.44%)
Injury, poisoning and procedural complications			
Accidental overdose subjects affected / exposed occurrences (all)	4 / 148 (2.70%) 5	11 / 149 (7.38%) 11	5 / 135 (3.70%) 5
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	6 / 148 (4.05%) 8	10 / 149 (6.71%) 13	4 / 135 (2.96%) 4
Gastrointestinal disorders			
Constipation subjects affected / exposed occurrences (all)	6 / 148 (4.05%) 6	1 / 149 (0.67%) 1	4 / 135 (2.96%) 4
Dry mouth subjects affected / exposed occurrences (all)	7 / 148 (4.73%) 8	3 / 149 (2.01%) 3	14 / 135 (10.37%) 14
Diarrhoea			

subjects affected / exposed occurrences (all)	1 / 148 (0.68%) 1	5 / 149 (3.36%) 5	7 / 135 (5.19%) 8
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	8 / 148 (5.41%)	6 / 149 (4.03%)	3 / 135 (2.22%)
occurrences (all)	9	6	3
Upper respiratory tract infection			
subjects affected / exposed	0 / 148 (0.00%)	3 / 149 (2.01%)	2 / 135 (1.48%)
occurrences (all)	0	3	2
Urinary tract infection			
subjects affected / exposed	8 / 148 (5.41%)	6 / 149 (4.03%)	4 / 135 (2.96%)
occurrences (all)	8	6	5

Non-serious adverse events	Part 1: vibegron 50 mg + tolterodine ER 4 mg/vibegron 50 mg	Part 2: placebo	Part 2: vibegron 100 mg + tolterodine ER 4 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 134 (20.15%)	6 / 64 (9.38%)	20 / 110 (18.18%)
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	2 / 134 (1.49%)	0 / 64 (0.00%)	1 / 110 (0.91%)
occurrences (all)	2	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 134 (4.48%)	2 / 64 (3.13%)	7 / 110 (6.36%)
occurrences (all)	7	4	7
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	6 / 134 (4.48%)	2 / 64 (3.13%)	4 / 110 (3.64%)
occurrences (all)	6	2	4
Dry mouth			
subjects affected / exposed	11 / 134 (8.21%)	4 / 64 (6.25%)	13 / 110 (11.82%)
occurrences (all)	11	4	14
Diarrhoea			
subjects affected / exposed	6 / 134 (4.48%)	0 / 64 (0.00%)	1 / 110 (0.91%)
occurrences (all)	6	0	1
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	3 / 134 (2.24%) 4	0 / 64 (0.00%) 0	2 / 110 (1.82%) 2
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 134 (0.75%) 1	0 / 64 (0.00%) 0	0 / 110 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	7 / 134 (5.22%) 8	2 / 64 (3.13%) 2	5 / 110 (4.55%) 5

Non-serious adverse events	Part 2: tolterodine ER 4 mg	Part 2: vibegron 100 mg	Extension Study: tolterodine ER 4 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	21 / 122 (17.21%)	5 / 112 (4.46%)	70 / 240 (29.17%)
Injury, poisoning and procedural complications Accidental overdose subjects affected / exposed occurrences (all)	1 / 122 (0.82%) 1	0 / 112 (0.00%) 0	1 / 240 (0.42%) 2
Nervous system disorders Headache subjects affected / exposed occurrences (all)	5 / 122 (4.10%) 6	2 / 112 (1.79%) 2	6 / 240 (2.50%) 7
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Dry mouth subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	1 / 122 (0.82%) 1 8 / 122 (6.56%) 8 2 / 122 (1.64%) 2	1 / 112 (0.89%) 1 1 / 112 (0.89%) 1 0 / 112 (0.00%) 0	9 / 240 (3.75%) 9 18 / 240 (7.50%) 18 10 / 240 (4.17%) 10
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection	1 / 122 (0.82%) 1	4 / 112 (3.57%) 4	20 / 240 (8.33%) 25

subjects affected / exposed	1 / 122 (0.82%)	1 / 112 (0.89%)	10 / 240 (4.17%)
occurrences (all)	1	1	10
Urinary tract infection			
subjects affected / exposed	8 / 122 (6.56%)	2 / 112 (1.79%)	27 / 240 (11.25%)
occurrences (all)	8	2	44

Non-serious adverse events	Extension Study: vibegron 100 mg	Extension Study: vibegron 50 mg	Extension Study: vibegron 100 mg + tolterodine ER 4 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	73 / 248 (29.44%)	59 / 223 (26.46%)	38 / 134 (28.36%)
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	4 / 248 (1.61%)	7 / 223 (3.14%)	1 / 134 (0.75%)
occurrences (all)	4	8	1
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 248 (1.61%)	13 / 223 (5.83%)	5 / 134 (3.73%)
occurrences (all)	4	13	5
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	7 / 248 (2.82%)	2 / 223 (0.90%)	9 / 134 (6.72%)
occurrences (all)	7	2	9
Dry mouth			
subjects affected / exposed	8 / 248 (3.23%)	8 / 223 (3.59%)	6 / 134 (4.48%)
occurrences (all)	8	8	6
Diarrhoea			
subjects affected / exposed	9 / 248 (3.63%)	9 / 223 (4.04%)	2 / 134 (1.49%)
occurrences (all)	10	9	4
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	24 / 248 (9.68%)	12 / 223 (5.38%)	15 / 134 (11.19%)
occurrences (all)	30	18	19
Upper respiratory tract infection			
subjects affected / exposed	14 / 248 (5.65%)	9 / 223 (4.04%)	9 / 134 (6.72%)
occurrences (all)	14	9	9
Urinary tract infection			

subjects affected / exposed	22 / 248 (8.87%)	27 / 223 (12.11%)	8 / 134 (5.97%)
occurrences (all)	33	42	8

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 March 2011	Extension Study, Amendment 008-10. The primary reason for this amendment was to add the 12-month safety and efficacy extension to the base study 008-00. Patients completing the base had the opportunity to receive an additional 1 year of treatment if they participated in the extension.
16 May 2012	Extension Study, Amendment 008-11. The primary reason for this amendment was to update the extension study protocol with the dose of vibegron 100 mg that patients enrolled in Part 2 of the base study who completed it would receive in the extension. Vibegron 100 mg was updated as the monotherapy dose and the dose to be administered concomitantly with tolterodine ER 4 mg. The protocol previously had indicated "X" mg.
16 May 2012	Base Study, Amendment 008-02. The primary reasons for this amendment were as follows: 1) To allow for the inclusion of women of childbearing potential, expanding the age range from 40-75 to 18-75. 2) To update the base protocol with the dose of vibegron for Part 2 of the base study. Vibegron 100 mg was selected as the monotherapy dose and the dose to be administered concomitantly with tolterodine ER 4 mg. The protocol previously had indicated "X" mg. 3) To remove the exclusion criteria that had prohibited use of beta-adrenergic blocking agents (beta blockers), calcium channel blockers, direct acting vasodilators, angiotensin converting enzyme (ACE) inhibitors, and angiotensin II receptor antagonists.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported