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Trial record **1 of 1** for: CQMF149E2203

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Efficacy, Safety and Pharmacokinetics of Indacaterol Acetate in Patients With Persistent Asthma

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01609478

First received: April 23, 2012
Last updated: January 15, 2015
Last verified: January 2015
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

Results First Received: June 27, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Asthma
Interventions:	Drug: indacaterol Drug: placebo Drug: mometasone furoate

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Participant Flow: Overall Study

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
STARTED	**111**	**108**	**116**
Full Analysis Set (FAS)	**110**	**108**	**115**
COMPLETED	**104**	**106**	**107**
NOT COMPLETED	**7**	**2**	**9**
Adverse Event	**3**	**1**	**5**

Protocol Deviation	**0**	**1**	**1**
Non-Compliance with study treatment	**1**	**0**	**0**
Physician Decision	**1**	**0**	**1**
Withdrawal by Subject	**2**	**0**	**2**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Total	Total of all reporting groups

Baseline Measures

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo	Total
Number of Participants [units: participants]	**111**	**108**	**116**	**335**

Age [units: years] Mean (Standard Deviation)	**50.7 (14.74)**	**48.1 (13.53)**	**49.8 (12.96)**	**49.6 (13.76)**
Gender [units: participants]				
Female	**59**	**60**	**61**	**180**
Male	**52**	**48**	**55**	**155**

Outcome Measures

Hide All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in One Second (FEV1) After 12 Weeks (Day 85) [Time Frame: after 12 weeks (Day 85)]

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in One Second (FEV1) After 12 Weeks (Day 85)
Measure Description	Forced Expiratory Volume in 1 second (FEV1) was measured via spirometry conducted according to internationally accepted standards. Trough FEV1 was defined as the average of measurements made 23 hours 10 minutes and 23 hours 45 minutes post-dose after 12 weeks (Day 85)
Time Frame	after 12 weeks (Day 85)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**107**	**104**	**111**
Trough Forced Expiratory Volume in One Second (FEV1) After 12 Weeks (Day 85) [units: Liters] Least Squares Mean (Standard Error)	**2.190 (0.0283)**	**2.216 (0.0281)**	**2.110 (0.0275)**

No statistical analysis provided for Trough Forced Expiratory Volume in One Second (FEV1) After 12 Weeks (Day 85)

2. Secondary: Asthma Control Questionnaire 5 (ACQ-5) After 12 Weeks (Day 85) [Time Frame: aftert 12 weeks (Day 85)]

Measure Type	Secondary
Measure Title	Asthma Control Questionnaire 5 (ACQ-5) After 12 Weeks (Day 85)
Measure Description	The Asthma Control Questionnaire (ACQ-5) is a validated questionnaire consisting of 5 items for the assessment of asthma symptom which are night symptom, morning symptom, limitation for the activities, shortness of breath, and wheeze. The ACQ-5 score is the mean of the 5 questions and therefore between 0 (totally controlled) and 6 (severely uncontrolled). A negative change in score indicates improvement in symptoms. MIXED model: Change from baseline

	in ACQ-5 = treatment + gender + baseline ACQ-5 score + age + level of asthma control + region + center (region) + error. Center is included as a random effect nested within region.
Time Frame	aftert 12 weeks (Day 85)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	**Indacaterol Acetate 150 µg**	**Placebo**
Number of Participants Analyzed [units: participants]	**103**	**104**	**108**
Asthma Control Questionnaire 5 (ACQ-5) After 12 Weeks (Day 85) [units: Units on a Scale] Least Squares Mean (Standard Error)	**1.31 (0.094)**	**1.42 (0.093)**	**1.32 (0.092)**

No statistical analysis provided for Asthma Control Questionnaire 5 (ACQ-5) After 12 Weeks (Day 85)

3. Secondary: Trough Forced Expiratory Volume in One Second (FEV1) After 2 Weeks (Day 15), 4 Weeks (Day 29), and 8 Weeks (Day 57) of Treatment. [Time Frame: Day 15, Day 29 and Day 57]

Measure Type	Secondary
Measure Title	Trough Forced Expiratory Volume in One Second (FEV1) After 2 Weeks (Day 15), 4 Weeks (Day 29), and 8 Weeks (Day 57) of Treatment.
Measure Description	Forced Expiratory Volume in 1 second (FEV1) was measured via spirometry conducted according to internationally accepted standards. Trough FEV1 was defined as the average of measurements made 23 hours 10 minutes and 23 hours 45 minutes post-dose after 2 weeks (Day 15), 4 weeks (Day 29), and 8 weeks (Day 57) of treatment.
Time Frame	Day 15, Day 29 and Day 57
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**107**	**104**	**111**
Trough Forced Expiratory Volume in One Second (FEV1) After 2 Weeks (Day 15), 4 Weeks (Day 29), and 8 Weeks (Day 57) of Treatment. [units: Liters] Least Squares Mean (Standard Error)			
Day 15	**2.169 (0.0259)**	**2.198 (0.0260)**	**2.069 (0.0253)**
Day 29	**2.180 (0.0274)**	**2.196 (0.0276)**	**2.057 (0.0266)**
Day 57	**2.180 (0.0281)**	**2.227 (0.0281)**	**2.099 (0.0273)**

No statistical analysis provided for Trough Forced Expiratory Volume in One Second (FEV1) After 2 Weeks (Day 15), 4 Weeks (Day 29), and 8 Weeks (Day 57) of Treatment.

4. Secondary: Forced Vital Capacity (FVC) on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85 at All Time Points [Time Frame: Day 1, Day 2, Day 14, Day 15, Day 84, Day 85]

Measure Type	Secondary
Measure Title	Forced Vital Capacity (FVC) on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85 at All Time Points
Measure Description	Forced Vital Capacity (FVC) was measured via spirometry conducted according to internationally accepted standards. FVC is measured on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85 at all time points
Time Frame	Day 1, Day 2, Day 14, Day 15, Day 84, Day 85

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Forced Vital Capacity (FVC) on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85 at All Time Points [units: liters] Least Squares Mean (Standard Error)			
Day 1 / 5 min post-dose (n=107,105,111)	**3.342 (0.0198)**	**3.338 (0.0198)**	**3.235 (0.0190)**
Day 1 / 15 min post-dose (n=107,105,111)	**3.372 (0.0240)**	**3.348 (0.0241)**	**3.238 (0.0232)**

Day 1 / 30 min post-dose (n=107,104,111)	**3.378 (0.0236)**	**3.367 (0.0236)**	**3.239 (0.0227)**
Day 1 / 1 hr post-dose (n=107,104,111)	**3.356 (0.0237)**	**3.333 (0.0239)**	**3.241 (0.0229)**
Day 1 / 2 hr post-dose (n=106,104,111)	**3.366 (0.0256)**	**3.367 (0.0258)**	**3.268 (0.0247)**
Day 1 / 4 hr post-dose (n=107,101,111)	**3.346 (0.0304)**	**3.342 (0.0307)**	**3.238 (0.0290)**
Day 1 / 6 hr post-dose (n=24,24,26)	**3.299 (0.0545)**	**3.345 (0.0507)**	**3.280 (0.0509)**
Day 2 / 23 hr 10min post-dose (n=107,104,110)	**3.314 (0.0282)**	**3.303 (0.0290)**	**3.254 (0.0279)**
Day 2 / 23 hr 45min post-dose (n=107,104,111)	**3.313 (0.0309)**	**3.341 (0.0314)**	**3.269 (0.0297)**
Day 14 / 5 min post-dose (n=107,105,111)	**3.404 (0.0327)**	**3.364 (0.0332)**	**3.212 (0.0326)**
Day 14 / 15 min post-dose (n=107,105,111)	**3.397 (0.0340)**	**3.377 (0.0343)**	**3.213 (0.0336)**
Day 14 / 30 min post-dose (n=107,104,111)	**3.412 (0.0341)**	**3.389 (0.0345)**	**3.246 (0.0336)**
Day 14 / 1 hr post-dose (n=107,104,111)	**3.408 (0.0324)**	**3.379 (0.0327)**	**3.206 (0.0319)**
Day 14 / 2 hr post-dose (n=106,104,111)	**3.402 (0.0325)**	**3.395 (0.0329)**	**3.207 (0.0323)**
Day 14 / 4 hr post-dose (n=107,101,111)	**3.368 (0.0329)**	**3.338 (0.0336)**	**3.217 (0.0323)**
Day 14 / 6 hr post-dose (n=24,24,26)	**3.332 (0.0620)**	**3.426 (0.0584)**	**3.257 (0.0602)**
Day 15 / 23 hr 10min post-dose (n=107,104,110)	**3.324 (0.0298)**	**3.311 (0.0302)**	**3.237 (0.0294)**

Day 15 / 23 hr 45min post-dose (n=107,104,111)	**3.347 (0.0307)**	**3.313 (0.0311)**	**3.260 (0.0301)**
Day 84 / 5 min post-dose (n=107,105,111)	**3.381 (0.0331)**	**3.374 (0.0335)**	**3.263 (0.0331)**
Day 84 / 15 min post-dose (n=107,105,111)	**3.393 (0.0353)**	**3.392 (0.0355)**	**3.275 (0.0351)**
Day 84 / 30 min post-dose (n=107,104,111)	**3.424 (0.0350)**	**3.399 (0.0352)**	**3.282 (0.0349)**
Day 84 / 1hr post-dose (n=107,104,111)	**3.394 (0.0339)**	**3.393 (0.0346)**	**3.262 (0.0336)**
Day 84 / 2 hr post-dose (n=106,104,111)	**3.413 (0.0334)**	**3.382 (0.0335)**	**3.292 (0.0332)**
Day 84 / 4 hr post-dose (n=106,101,111)	**3.346 (0.0350)**	**3.363 (0.0356)**	**3.257 (0.0349)**
Day 85 / 23 hr 10min post-dose (n=107,104,110)	**3.350 (0.0342)**	**3.300 (0.0347)**	**3.287 (0.0339)**
Day 85 / 23 hr 45min post-dose (n=107,104,111)	**3.343 (0.0367)**	**3.321 (0.0368)**	**3.294 (0.0360)**

No statistical analysis provided for Forced Vital Capacity (FVC) on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85 at All Time Points

5. Secondary: Forced Expiratory Volume in One Second (FEV1)/ Forced Vital Capacity (FVC) on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85
[Time Frame: Day 1, Day 2, Day 14, Day 15, Day 84, Day 85]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in One Second (FEV1)/ Forced Vital Capacity (FVC) on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85

Measure Description	Forced Expiratory Volume in 1 second (FEV1)/Forced Vital Capacity (FVC) was measured via spirometry conducted according to internationally accepted standards.
Time Frame	Day 1, Day 2, Day 14, Day 15, Day 84, Day 85
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Forced Expiratory Volume in One Second (FEV1)/ Forced Vital Capacity (FVC) on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85 [units: ratio] Least Squares Mean (Standard Error)			
Day 1 / 5 min post-dose (n=107,105,111)	**65.608 (0.3659)**	**66.049 (0.3641)**	**63.461**

			(0.3508)
Day 1 / 15 min post-dose (n=107,105,111)	65.602 (0.3854)	67.039 (0.3898)	63.537 (0.3759)
Day 1 / 30 min post-dose (n=107,104,111)	65.738 (0.4626)	67.189 (0.4607)	63.767 (0.4454)
Day 1 / 1 hr post-dose (n=107,104,111)	66.089 (0.4465)	67.620 (0.4485)	63.744 (0.4298)
Day 1 / 2 hr post-dose (n=106,104,111)	66.607 (0.4705)	67.824 (0.4727)	64.141 (0.4534)
Day 1 / 4 hr post-dose (n=107,101,111)	66.094 (0.5098)	67.968 (0.5137)	64.212 (0.4871)
Day 1 / 6 hr post-dose (n=24,24,26)	64.716 (0.9815)	68.846 (0.9220)	63.773 (0.9135)
Day 2 / 23 hr 10min post-dose (n=107,104,110)	65.465 (0.5112)	66.942 (0.5197)	63.822 (0.5006)
Day 2 / 23 hr 45min post-dose (n=107,104,111)	65.809 (0.5299)	66.791 (0.5323)	63.741 (0.5057)
Day 14 / 5 min post-dose (n=107,105,111)	66.548 (0.5102)	67.366 (0.5172)	64.362 (0.5075)
Day 14 / 15 min post-dose (n=107,105,111)	67.187 (0.5042)	67.577 (0.5093)	64.702 (0.4986)
Day 14 / 30 min post-dose (n=107,104,111)	67.024 (0.5601)	67.765 (0.5633)	64.192 (0.5476)
Day 14 / 1 hr post-dose (n=107,104,111)	67.100 (0.5446)	68.262 (0.5476)	64.383 (0.5327)
Day 14 / 2 hr post-dose (n=106,104,111)	67.538 (0.5486)	68.397 (0.5540)	64.617 (0.5431)
Day 14 / 4 hr post-dose (n=107,101,111)	66.866 (0.5763)	68.044 (0.5871)	64.426 (0.5632)

Day 14 / 6 hr post-dose (n=24,24,26)	**64.792 (1.0246)**	**67.346 (0.9676)**	**64.167 (0.9834)**
Day 15 / 23 hr 10min post-dose (n=107,104,110)	**65.436 (0.5564)**	**65.930 (0.5597)**	**64.027 (0.5455)**
Day 15 / 23 hr 45min post-dose (n=107,104,111)	**65.606 (0.5871)**	**66.435 (0.5887)**	**63.726 (0.5729)**
Day 84 / 5 min post-dose (n=107,105,111)	**67.040 (0.5442)**	**67.762 (0.5498)**	**64.850 (0.5422)**
Day 84 / 15 min post-dose (n=107,105,111)	**67.162 (0.5671)**	**67.907 (0.5719)**	**65.074 (0.5646)**
Day 84 / 30 min post-dose (n=107,104,111)	**66.936 (0.6017)**	**67.865 (0.6031)**	**64.848 (0.5966)**
Day 84 / 1hr post-dose (n=107,104,111)	**3.394 (0.0339)**	**3.393 (0.0346)**	**3.262 (0.0336)**
Day 84 / 2 hr post-dose (n=106,104,111)	**3.413 (0.0334)**	**3.382 (0.0335)**	**3.292 (0.0332)**
Day 84 / 4 hr post-dose (n=106,101,111)	**3.346 (0.0350)**	**3.363 (0.0356)**	**3.257 (0.0349)**
Day 85 / 23 hr 10min post-dose (n=107,104,110)	**3.350 (0.0342)**	**3.300 (0.0347)**	**3.287 (0.0339)**
Day 85 / 23 hr 45min post-dose (n=107,104,111)	**3.343 (0.0367)**	**3.321 (0.0368)**	**3.294 (0.0360)**

No statistical analysis provided for Forced Expiratory Volume in One Second (FEV1)/ Forced Vital Capacity (FVC) on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85

6. Secondary: Forced Expiratory Flow (FEF 25-75%)on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85 [Time Frame: Day 1, Day 2, Day 14, Day 15, Day 84, Day 85]

Measure Type	Secondary
Measure Title	Forced Expiratory Flow (FEF 25-75%)on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85
Measure Description	Forced Expiratory Flow (FEF 25-75%) was measured via spirometry conducted according to internationally accepted standards.
Time Frame	Day 1, Day 2, Day 14, Day 15, Day 84, Day 85
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	**Indacaterol Acetate 150 µg**	**Placebo**
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Forced Expiratory Flow (FEF 25-75%)on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85			

[units: liters/second] Least Squares Mean (Standard Error)			
Day 1 / 5 min post-dose (n=107,105,111)	1.420 (0.0237)	1.485 (0.0235)	1.295 (0.0226)
Day 1 / 15 min post-dose (n=107,105,111)	1.449 (0.0254)	1.563 (0.0256)	1.295 (0.0247)
Day 1 / 30 min post-dose (n=107,104,111)	1.467 (0.0290)	1.568 (0.0290)	1.310 (0.0280)
Day 1 / 1 hr post-dose (n=107,104,111)	1.471 (0.0307)	1.594 (0.0309)	1.297 (0.0296)
Day 1 / 2 hr post-dose (n=106,104,111)	1.508 (0.0307)	1.632 (0.0310)	1.348 (0.0297)
Day 1 / 4 hr post-dose (n=107,101,111)	1.479 (0.0327)	1.625 (0.0331)	1.329 (0.0313)
Day 1 / 6 hr post-dose (n=24,24,26)	1.364 (0.0889)	1.620 (0.0840)	1.332 (0.0832)
Day 2 / 23 hr 10min post-dose (n=107,104,110)	1.407 (0.0322)	1.520 (0.0328)	1.310 (0.0315)
Day 2 / 23 hr 45min post-dose (n=107,104,111)	1.436 (0.0399)	1.524 (0.0401)	1.326 (0.0382)
Day 14 / 5 min post-dose (n=107,105,111)	1.505 (0.0350)	1.571 (0.0354)	1.318 (0.0348)
Day 14 / 15 min post-dose (n=107,105,111)	1.540 (0.0366)	1.597 (0.0370)	1.351 (0.0362)
Day 14 / 30 min post-dose (n=107,104,111)	1.532 (0.0383)	1.607 (0.0386)	1.336 (0.0376)
Day 14 / 1 hr post-dose (n=107,104,111)	1.569 (0.0400)	1.664 (0.0402)	1.343 (0.0391)
			1.338

Day 14 / 2 hr post-dose (n=106,104,111)	**1.551 (0.0380)**	**1.676 (0.0385)**	**(0.0379)**
Day 14 / 4 hr post-dose (n=107,101,111)	**1.526 (0.0434)**	**1.628 (0.0445)**	**1.339 (0.0426)**
Day 14 / 6 hr post-dose (n=24,24,26)	**1.370 (0.0843)**	**1.519 (0.0792)**	**1.363 (0.0808)**
Day 15 / 23 hr 10min post-dose (n=107,104,110)	**1.421 (0.0383)**	**1.442 (0.0386)**	**1.315 (0.0377)**
Day 15 / 23 hr 45min post-dose (n=107,104,111)	**1.430 (0.0431)**	**1.492 (0.0431)**	**1.319 (0.0420)**
Day 84 / 5 min post-dose (n=107,105,111)	**1.535 (0.0391)**	**1.627 (0.0394)**	**1.363 (0.0390)**
Day 84 / 15 min post-dose (n=107,105,111)	**1.530 (0.0393)**	**1.675 (0.0396)**	**1.372 (0.0392)**
Day 84 / 30 min post-dose (n=107,104,111)	**1.548 (0.0412)**	**10659 (0.0414)**	**1.368 (0.0411)**
Day 84 / 1hr post-dose (n=107,104,111)	**1.578 (0.0408)**	**1.687 (0.0415)**	**1.404 (0.0404)**
Day 84 / 2 hr post-dose (n=106,104,111)	**1.571 (0.0409)**	**1.704 (0.0411)**	**1.382 (0.0409)**
Day 84 / 4 hr post-dose (n=106,101,111)	**1.548 (0.0398)**	**1.648 (0.0405)**	**1.350 (0.397)**
Day 85 / 23 hr 10min post-dose (n=107,104,110)	**1.437 (0.0378)**	**1.507 (0.0380)**	**1.328 (0.0373)**
Day 85 / 23 hr 45min post-dose (n=107,104,111)	**1.476 (0.0428)**	**1.496 (0.0427)**	**1.378 (0.0418)**

No statistical analysis provided for Forced Expiratory Flow (FEF 25-75%)on Day 1, Day 2, Day 14, Day 15, Day 84, Day 85

7. Secondary: Standardized Forced Expiratory Volume in One Second (FEV1) Area Under the Curve (AUC) at (5 Min - 4 h), (5 Min - 1 h) (1 h - 4 h) Measured on Day 1, 2 Weeks (Day 14)&12 Weeks (Day 84) [Time Frame: Day 1, 2 Weeks, 12 Weeks]

Measure Type	Secondary
Measure Title	Standardized Forced Expiratory Volume in One Second (FEV1) Area Under the Curve (AUC) at (5 Min - 4 h), (5 Min - 1 h) (1 h - 4 h) Measured on Day 1, 2 Weeks (Day 14)&12 Weeks (Day 84)
Measure Description	Forced Expiratory Volume in 1 second (FEV1)/Area Under the Curve(AUC) was measured via spirometry conducted according to internationally accepted standards.FEV1 AUC(5 min - 4 h), (5 min - 1 h) and (1 h - 4 h) are measured at Day 1, 2 Weeks (Day 14) and 12 Weeks (Day84) and defined as average of FEV1 at specified timepoints above.
Time Frame	Day 1, 2 Weeks, 12 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	**Indacaterol Acetate 150**	**Placebo**

		µg	
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Standardized Forced Expiratory Volume in One Second (FEV1) Area Under the Curve (AUC) at (5 Min - 4 h), (5 Min - 1 h) (1 h - 4 h) Measured on Day 1, 2 Weeks (Day 14)&12 Weeks (Day 84) [units: Liters] Least Squares Mean (Standard Error)			
Day 1 (5min-4h) (n=107,105,111)	**2.209 (0.0170)**	**2.274 (0.0169)**	**2.077 (0.0163)**
Day 1 (5min-1h) (n=107,105,111)	**2.198 (0.0165)**	**2.253 (0.0164)**	**2.059 (0.0158)**
Day 1 (1h-4h) (n=107,104,111)	**2.212 (0.0182)**	**2.284 (0.0183)**	**2.082 (0.0175)**
Day 14 (5min-4h) (n=107,105,111)	**2.265 (0.0244)**	**2.313 (0.0246)**	**2.074 (0.0240)**
Day 14 (5min-1h) (n=107,105,111)	**2.267 (0.0245)**	**2.299 (0.0246)**	**2.069 (0.0241)**
Day 14 (1h-4h) (n=107,104,111)	**2.262 (0.0247)**	**2.318 (0.0250)**	**2.066 (0.0244)**
Day 84 (5min-4h) (n=107,105,111)	**2.264 (0.0259)**	**2.322 (0.0260)**	**2.132 (0.0257)**
Day 84 (5min-1h) (n=107,105,111)	**2.265 (0.0271)**	**2.321 (0.0272)**	**2.119 (0.0270)**

Day 84 (1h-4h) (n=107,104,111)	**2.263 (0.0258)**	**2.322 (0.0260)**	**2.130 (0.0257)**

No statistical analysis provided for Standardized Forced Expiratory Volume in One Second (FEV1) Area Under the Curve (AUC) at (5 Min - 4 h), (5 Min - 1 h) (1 h - 4 h) Measured on Day 1, 2 Weeks (Day 14)&12 Weeks (Day 84)

8. Secondary: Peak Forced Expiratory Volume in 1 Second (FEV1) at Day 1, 2 Weeks (Day 14), 12 Weeks (Day 84) [Time Frame: Day 1, 2 weeks (Day 14), 12 weeks (Day 84)]

Measure Type	Secondary
Measure Title	Peak Forced Expiratory Volume in 1 Second (FEV1) at Day 1, 2 Weeks (Day 14), 12 Weeks (Day 84)
Measure Description	Peak Forced Expiratory Volume in 1 second (FEV1) was measured via spirometry conducted according to internationally accepted standards. Peak FEV1 is defined as the maximum FEV1 during the first 4 h post morning dosing at Day 1, 2Weeks and 12 Weeks.
Time Frame	Day 1, 2 weeks (Day 14), 12 weeks (Day 84)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Peak Forced Expiratory Volume in 1 Second (FEV1) at Day 1, 2 Weeks (Day 14), 12 Weeks (Day 84) [units: liters] Least Squares Mean (Standard Error)			
Day 1	**2.287 (0.0183)**	**2.353 (0.0182)**	**2.172 (0.0176)**
Day 14	**2.345 (0.0252)**	**2.387 (0.0254)**	**2.165 (0.0248)**
Day 84	**2.345 (0.0272)**	**2.403 (0.0273)**	**2.215 (0.0270)**

No statistical analysis provided for Peak Forced Expiratory Volume in 1 Second (FEV1) at Day 1, 2 Weeks (Day 14), 12 Weeks (Day 84)

9. Secondary: Asthma Control Questionnaire 5 (ACQ-5) After 4 Weeks (Day 29) and After 8 Weeks (Day 57) of Treatment [Time Frame: after 4 weeks (Day 29) and after 8 weeks (Day 57)]

Measure Type	Secondary
Measure Title	Asthma Control Questionnaire 5 (ACQ-5) After 4 Weeks (Day 29) and After 8 Weeks (Day 57) of Treatment
Measure Description	The ACQ-5 is a validated questionnaire consisting of 5 items for the assessment of asthma symptom which are night

	symptom, morning symptom, limitation for the activities, shortness of breath, and wheeze. Each item is graded on a scale of 0-6 and the questions are equally weighted. The ACQ-5 score is the mean of the 5 questions and therefore between 0 (totally controlled) and 6 (severely uncontrolled).
Time Frame	after 4 weeks (Day 29) and after 8 weeks (Day 57)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	**Indacaterol Acetate 150 µg**	**Placebo**
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Asthma Control Questionnaire 5 (ACQ-5) After 4 Weeks (Day 29) and After 8 Weeks (Day 57) of Treatment [units: units on a scale] Least Squares Mean (Standard Error)			

Day 29 (n=103, 104, 108)	**1.43 (0.088)**	**1.39 (0.088)**	**1.55 (0.086)**
Day 57 (n= 103, 104, 108)	**1.42 (0.093)**	**1.29 (0.093)**	**1.46 (0.091)**

No statistical analysis provided for Asthma Control Questionnaire 5 (ACQ-5) After 4 Weeks (Day 29) and After 8 Weeks (Day 57) of Treatment

10. Secondary: Morning and Evening Peak Expiratory Flow Rate (PEFR) Over 12 Weeks of Treatment. This is LS Mean of the Treatment Period. [Time Frame: baseline, 4weeks, 8 weeks and 12 weeks]

Measure Type	Secondary
Measure Title	Morning and Evening Peak Expiratory Flow Rate (PEFR) Over 12 Weeks of Treatment. This is LS Mean of the Treatment Period.
Measure Description	PEFR is measured with portable spirometer by participants every morning and evening at home.
Time Frame	baseline, 4weeks, 8 weeks and 12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Morning and Evening Peak Expiratory Flow Rate (PEFR) Over 12 Weeks of Treatment. This is LS Mean of the Treatment Period. [units: liters/second] Least Squares Mean (Standard Error)			
Morning Baseline - <4 weeks (n=104,100,109)	**326.98 (3.741)**	**335.44 (3.842)**	**307.68 (3.636)**
Evening baseline - <4 weeks (n=104,100,109)	**332.96 (3.477)**	**345.99 (3.587)**	**312.42 (3.545)**
Morning 4 weeks - <8 weeks (n=104,100,109)	**328.45 (4.374)**	**338.23 (4.466)**	**315.60 (4.248)**
Evening 4 weeks - <8 weeks (n=104,100,109)	**333.36 (4.221)**	**344.63 (4.323)**	**313.31 (4.284)**
Morning 8 weeks - <12 weeks (n=104,100,109)	**329.85 (4.699)**	**334.83 (4.783)**	**317.03 (4.559)**
Evening 8 weeks - <12 weeks (n=104,100,109)	**332.61 (4.628)**	**342.40 (4.718)**	**316.28 (4.677)**

No statistical analysis provided for Morning and Evening Peak Expiratory Flow Rate (PEFR) Over 12 Weeks of Treatment. This is LS Mean of the Treatment Period.

11. Secondary: The Usage of Rescue Medication (Short Acting β2-agonist) Over 12 Weeks of Treatment [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	The Usage of Rescue Medication (Short Acting β2-agonist) Over 12 Weeks of Treatment
Measure Description	Participants record the number of puffs of rescue medication taken in the previous 12 hours in the morning and nighttime.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	**Indacaterol Acetate 150 µg**	**Placebo**
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**

The Usage of Rescue Medication (Short Acting β2-agonist) Over 12 Weeks of Treatment [units: number of puffs] Least Squares Mean (Standard Deviation)			
Mean daily number of puffs (n=105, 102, 105)	**1.08 (0.132)**	**0.99 (0.136)**	**1.31 (0.132)**
Mean Daytime number of puffs (n=103, 99, 100)	**0.54 (0.074)**	**0.55 (0.077)**	**0.73 (0.076)**
Mean nighttime number of puffs (n=104, 100, 107)	**0.55 (0.063)**	**0.47 (0.065)**	**0.64 (0.062)**

No statistical analysis provided for The Usage of Rescue Medication (Short Acting β2-agonist) Over 12 Weeks of Treatment

12. Secondary: Asthma Quality of Life Questionnaire (AQLQ(S)) After 4 Weeks (Day 29) and 12 Weeks (Day 85) of Treatment [Time Frame: 4 Weeks, 12 Weeks]

Measure Type	Secondary
Measure Title	Asthma Quality of Life Questionnaire (AQLQ(S)) After 4 Weeks (Day 29) and 12 Weeks (Day 85) of Treatment
Measure Description	The AQLQ is a 32-item disease specific questionnaire designed to measure functional impairments in asthma. Patients are asked to score each item on a 7-point scale based on the experience of last 2 weeks. The overall AQLQ score is the mean response to all 32 questions. Therefore, the possible highest score (better) would be 7 and the lowest (worse) would be 1. Changes in scores of 0.5 to 1.0 are considered clinically meaningful; 1.0 to 1.5 as moderate and > 1.5 as marked clinically important differences for any individual domain or for the overall summary score.
Time Frame	4 Weeks, 12 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.

The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Asthma Quality of Life Questionnaire (AQLQ(S)) After 4 Weeks (Day 29) and 12 Weeks (Day 85) of Treatment [units: Units on a Scale] Least Squares Mean (Standard Error)			
Day 29 (n=103,104, 108)	**5.52 (0.082)**	**5.48 (0.082)**	**5.38 (0.080)**
Day 85 (n=103,104, 108)	**5.64 (0.088)**	**5.47 (0.087)**	**5.60 (0.086)**

No statistical analysis provided for Asthma Quality of Life Questionnaire (AQLQ(S)) After 4 Weeks (Day 29) and 12 Weeks (Day 85) of Treatment

13. Secondary: Time to First Asthma Exacerbation (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Time to First Asthma Exacerbation (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period
Measure Description	Duration of treatment until first asthma exacerbation by severity of exacerbation. A severe asthma exacerbation is systemic corticosteroids (SCS) use ≥3 days and hospitalization or emergency department visit (greater than 24 h) or death due to asthma. A moderate asthma exacerbation is SCS use ≥3 days either as an outpatient or in emergency department visits (less than or equal to 24 h). Worsening of asthma not requiring more than 3 days of SCS or hospitalization/emergency room will be considered mild asthma exacerbations.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Time to First Asthma Exacerbation (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period [units: weeks] Median (95% Confidence Interval)			
Moderate or Severe exacerbation	**NA** [1]	**NA** [1]	**NA** [1]
Any Asthma Exacerbation	**NA** [1]	**NA** [1]	**NA** [1]
Mild Asthma Exacerbation	**NA** [1]	**NA** [1]	**NA** [1]
Moderate Asthma Exacerbation	**NA** [1]	**NA** [1]	**NA** [1]
Severe Asthma Exacerbation	**NA** [1]	**NA** [1]	**NA** [1]

[1] There were too few events to calculate the median.

No statistical analysis provided for Time to First Asthma Exacerbation (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period

14. Secondary: The Annual Rate of Asthma Exacerbations (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period [Time Frame: 12 weeks]

Measure Type	Secondary

Measure Title	The Annual Rate of Asthma Exacerbations (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period
Measure Description	Annual incidence rate of asthma exacerbation by severity of exacerbation. The number of asthma exacerbation is used to calculate annual incidence rate. A severe asthma exacerbation is SCS use ≥3 days and hospitalization or emergency department visit (greater than 24 h) or death due to asthma. A moderate asthma exacerbation is SCS use ≥3 days either as an outpatient or in emergency department visits (less than or equal to 24 h). Worsening of asthma not requiring more than 3 days of SCS or hospitalization/emergency room will be considered mild asthma exacerbations. Number of the asthma exacerbation will be analyzed by the negative binomial regression including treatment, history of asthma exacerbation in the 12 months prior to screening and region as factors and FEV1 prior to inhalation and FEV1 30 min post inhalation of salbutamol/albuterol (components of SABA reversibility) as covariates. The estimates are obtained from the model and so we cannot specify a formula.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol	**Indacaterol**	

	Acetate 75 µg	Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
The Annual Rate of Asthma Exacerbations (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period [units: # of exacerbations] Number (95% Confidence Interval)			
Moderate or Severe Exacerbation	**0.315 (0.1184 to 0.8387)**	**0.353 (0.1373 to 0.9053)**	**0.352 (0.1406 to 0.8805)**
Any asthma exacerbation	**0.421 (0.1711 to 1.0358)**	**0.569 (0.2389 to 1.3553)**	**0.788 (0.3486 to 1.7827)**
Mild Asthma Exacerbation	**0.000** [1]	**0.001** [1]	**0.001** [1]
Moderate Asthma Exacerbation	**0.225 (0.0790 to 0.6403)**	**0.320 (0.1239 to 0.8251)**	**0.274 (0.1017 to 0.7387)**
Severe Asthma Exacerbation	**0.000** [1]	**0.000** [1]	**0.000** [1]

[1] upper limit infinity

No statistical analysis provided for The Annual Rate of Asthma Exacerbations (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period

15. Secondary: Duration of Asthma Exacerbations (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Duration of Asthma Exacerbations (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period
Measure Description	Duration of asthma exacerbations by severity of exacerbation. A severe asthma exacerbation is SCS use ≥3 days and hospitalization or emergency department visit (greater than 24 h) or death due to asthma. A moderate asthma exacerbation is SCS use ≥3 days either as an outpatient or in emergency department visits (less than or equal to 24 h). Worsening of asthma not requiring more than 3 days of SCS or hospitalization/emergency room will be considered mild asthma exacerbations.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol	**Indacaterol**	**Placebo**

	Acetate 75 µg	Acetate 150 µg	
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Duration of Asthma Exacerbations (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period [units: days] Mean (Standard Deviation)			
moderate or severe exacerbations	**0.7 (3.32)**	**0.6 (2.50)**	**0.8 (4.11)**
any asthma exacerbations	**1.0 (3.88)**	**0.9 (3.62)**	**1.3 (4.74)**
mild asthma exacerbations	**0.3 (2.11)**	**0.4 (2.47)**	**0.5 (2.54)**
moderate asthma exacerbations	**0.6 (3.26)**	**0.6 (2.50)**	**0.6 (3.53)**
Severe asthma exacerbations	**0.1 (0.67)**	**0.0 (0.00)**	**0.1 (1.59)**

No statistical analysis provided for Duration of Asthma Exacerbations (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period

16. Secondary: The Percentage of Patients With at Least One Asthma Exacerbation (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	The Percentage of Patients With at Least One Asthma Exacerbation (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period
Measure Description	The percentage of patients with at least one asthma exacerbation by severity of exacerbation. A severe asthma

	exacerbation is SCS use ≥3 days and hospitalization or emergency department visit (greater than 24 h) or death due to asthma. A moderate asthma exacerbation is SCS use ≥3 days either as an outpatient or in emergency department visits (less than or equal to 24 h). Worsening of asthma not requiring more than 3 days of SCS or hospitalization/emergency room will be considered mild asthma exacerbations.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**107**	**105**	**111**
The Percentage of Patients With at Least One Asthma Exacerbation (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period			

[units: percentage of participants]			
moderate or severe asthma exacerbations	5.6	5.7	4.5
any asthma exacerbations	8.4	8.6	9.9
mild asthma exacerbations	2.8	3.8	5.4
moderate asthma exacerbations	4.7	5.7	4.5
severe asthma exacerbations	0.9	0.0	0.9

No statistical analysis provided for The Percentage of Patients With at Least One Asthma Exacerbation (Mild, Moderate, Severe, Moderate or Severe and Any) Over the 12 Week Treatment Period

17. Secondary: Time to Permanent Study Discontinuation Due to Asthma Exacerbation Over the 12 Week Treatment Period [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Time to Permanent Study Discontinuation Due to Asthma Exacerbation Over the 12 Week Treatment Period
Measure Description	Time to permanent study discontinuation due to asthma exacerbation. A severe asthma exacerbation is SCS use ≥3 days and hospitalization or emergency department visit (greater than 24 h) or death due to asthma. A moderate asthma exacerbation is SCS use ≥3 days either as an outpatient or in emergency department visits (less than or equal to 24 h). Worsening of asthma not requiring more than 3 days of SCS or hospitalization/emergency room will be considered mild asthma exacerbations.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants

from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Time to Permanent Study Discontinuation Due to Asthma Exacerbation Over the 12 Week Treatment Period [units: days] Median (95% Confidence Interval)	**NA** [1]	**NA** [1]	**NA** [1]

[1] There were too few events to calculate the median.

No statistical analysis provided for Time to Permanent Study Discontinuation Due to Asthma Exacerbation Over the 12 Week Treatment Period

18. Secondary: The Percentage of Patients Who Permanently Discontinued Study Due to Asthma Exacerbation Over the 12 Week Treatment Period [Time Frame: 12 weeks]

Measure Type	Secondary

Measure Title	The Percentage of Patients Who Permanently Discontinued Study Due to Asthma Exacerbation Over the 12 Week Treatment Period
Measure Description	The percentage of patients who permanently discontinued study due to asthma exacerbation. A severe asthma exacerbation is SCS use ≥3 days and hospitalization or emergency department visit (greater than 24 h) or death due to asthma. A moderate asthma exacerbation is SCS use ≥3 days either as an outpatient or in emergency department visits (less than or equal to 24 h). Worsening of asthma not requiring more than 3 days of SCS or hospitalization/emergency room will be considered mild asthma exacerbations.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	**Indacaterol Acetate 150 µg**	**Placebo**
Number of Participants Analyzed			

[units: participants]	**107**	**105**	**111**
The Percentage of Patients Who Permanently Discontinued Study Due to Asthma Exacerbation Over the 12 Week Treatment Period [units: percentage of participants]	**1.9**	**1.0**	**3.6**

No statistical analysis provided for The Percentage of Patients Who Permanently Discontinued Study Due to Asthma Exacerbation Over the 12 Week Treatment Period

19. Secondary: Total Amounts (in Doses) of Systemic Corticosteroids Used to Treat Asthma Exacerbations Over the 12 Week Treatment Period [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Total Amounts (in Doses) of Systemic Corticosteroids Used to Treat Asthma Exacerbations Over the 12 Week Treatment Period
Measure Description	Total amounts (in doses) of systemic corticosteroids (SCS) used to treat asthma exacerbations.SCS includes Intramuscular (IM), Intravenous (IV) and Oral. A severe asthma exacerbation is SCS use ≥3 days and hospitalization or emergency department visit (greater than 24 h) or death due to asthma. A moderate asthma exacerbation is SCS use ≥3 days either as an outpatient or in emergency department visits (less than or equal to 24 h). Worsening of asthma not requiring more than 3 days of SCS or hospitalization/emergency room will be considered mild asthma exacerbations.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all randomized who received at least one dose of study drug with available data for analysis. Participants from FAS were considered for this analysis, however for a given time point participants analyzed had a value at such timepoint.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg	Placebo
Number of Participants Analyzed [units: participants]	**110**	**108**	**115**
Total Amounts (in Doses) of Systemic Corticosteroids Used to Treat Asthma Exacerbations Over the 12 Week Treatment Period [units: milligrams (mg)] Mean (Standard Deviation)			
IIntramuscular - Triamcinolone Acetonide	**NA [1]**	**20 [2]**	**0 [1]**
Intravenous - Betamethasone	**NA [1]**	**4 [2]**	**4 [2]**
Intravenous- Hydrocortisone	**500 [2]**	**100 [2]**	**200 [2]**
Intravenous- Hydrocortisone NA Succinate	**300 [2]**	**500 (141.421)**	**NA [1]**
Intravenous- Methylprednisolone NA Succinate	**60 (28.284)**	**80 [2]**	**NA [1]**
Oral- Methylprednisolone	**NA [1]**	**32 [2]**	**NA [1]**
Oral - Prednisolone	**60 (42.426)**	**90 [2]**	**37.50 (24.749)**

Oral - Prednisone	**40** [2]	**40 (0)**	**100 (70.11)**
Oral - Prednisone equivalent dose	**102 (66.765)**	**106.11 (104.055)**	**58.61 (49.956)**

[1] no participants in this treatment group took this SCS
[2] SD cannot be calculated as there was only one value

No statistical analysis provided for Total Amounts (in Doses) of Systemic Corticosteroids Used to Treat Asthma Exacerbations Over the 12 Week Treatment Period

20. Secondary: Plasma Indacaterol Concentrations at Day 1 and Day 14 [Time Frame: Day 1 and Day 14]

Measure Type	Secondary
Measure Title	Plasma Indacaterol Concentrations at Day 1 and Day 14
Measure Description	Maximum plasma concentration after drug administration (Cmax) was measured for indacaterol acetate 75 µg and indacaterol acetate 150 µg for Pharmacokinetic (PK) Subgroup
Time Frame	Day 1 and Day 14
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Pharmacokinetic (PK) profiling subgroup included all randomized patients who consented to participate in the additional PK assessment.

Reporting Groups

	Description
Indacaterol Acetate 75 µg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Indacaterol Acetate 150 µg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Measured Values

	Indacaterol Acetate 75 µg	Indacaterol Acetate 150 µg
Number of Participants Analyzed [units: participants]	**30**	**26**
Plasma Indacaterol Concentrations at Day 1 and Day 14 [units: pg/ml] Mean (Standard Deviation)		
Day 1 (n=21, 21)	**70.7 (29.1)**	**164 (69.5)**
Day 14 (n=21, 21)	**129 (48.6)**	**285 (108)**

No statistical analysis provided for Plasma Indacaterol Concentrations at Day 1 and Day 14

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Indacaterol Acetate 75 mcg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 mcg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Serious Adverse Events

	Indacaterol Acetate 75 mcg	Indacaterol Acetate 150 mcg	Placebo
Total, serious adverse events			
# participants affected / at risk	**2/110 (1.82%)**	**0/108 (0.00%)**	**2/115 (1.74%)**
Cardiac disorders			
ATRIAL FLUTTER † 1			
# participants affected / at risk	**0/110 (0.00%)**	**0/108 (0.00%)**	**1/115 (0.87%)**
Gastrointestinal disorders			
UMBILICAL HERNIA † 1			
# participants affected / at risk	**1/110 (0.91%)**	**0/108 (0.00%)**	**0/115 (0.00%)**
Infections and infestations			
BRONCHITIS † 1			
# participants affected / at risk	**1/110 (0.91%)**	**0/108 (0.00%)**	**0/115 (0.00%)**
Nervous system disorders			
CEREBRAL INFARCTION † 1			
# participants affected / at risk	**0/110 (0.00%)**	**0/108 (0.00%)**	**1/115 (0.87%)**
Respiratory, thoracic and mediastinal disorders			
ASTHMA † 1			
# participants affected / at risk	**1/110 (0.91%)**	**0/108 (0.00%)**	**1/115 (0.87%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	2%

Reporting Groups

	Description
Indacaterol Acetate 75 mcg	indacaterol acetate 75 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Indacaterol Acetate 150 mcg	indacaterol acetate 150 µg od delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od
Placebo	placebo delivered via Concept 1 inhaler Background therapy: mometasone furoate 200 mcg od

Other Adverse Events

	Indacaterol Acetate 75 mcg	Indacaterol Acetate 150 mcg	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**19/110 (17.27%)**	**20/108 (18.52%)**	**28/115 (24.35%)**
Infections and infestations			
NASOPHARYNGITIS † [1]			
# participants affected / at risk	**7/110 (6.36%)**	**6/108 (5.56%)**	**9/115 (7.83%)**
PHARYNGITIS † [1]			
# participants affected / at risk	**1/110 (0.91%)**	**1/108 (0.93%)**	**4/115 (3.48%)**

RHINITIS † 1			
# participants affected / at risk	**0/110 (0.00%)**	**3/108 (2.78%)**	**0/115 (0.00%)**
UPPER RESPIRATORY TRACT INFECTION † 1			
# participants affected / at risk	**1/110 (0.91%)**	**1/108 (0.93%)**	**4/115 (3.48%)**
Musculoskeletal and connective tissue disorders			
MYALGIA † 1			
# participants affected / at risk	**3/110 (2.73%)**	**0/108 (0.00%)**	**0/115 (0.00%)**
Nervous system disorders			
HEADACHE † 1			
# participants affected / at risk	**5/110 (4.55%)**	**2/108 (1.85%)**	**4/115 (3.48%)**
Respiratory, thoracic and mediastinal disorders			
ASTHMA † 1			
# participants affected / at risk	**8/110 (7.27%)**	**9/108 (8.33%)**	**12/115 (10.43%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Clinical Disclosure Office
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No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01609478 History of Changes
Other Study ID Numbers:	**CQMF149E2203** 2012-000520-18 (EudraCT Number)
Study First Received:	April 23, 2012
Results First Received:	June 27, 2014

Last Updated:	January 15, 2015
Health Authority:	United States: Food and Drug Administration Canada: Health Canada Germany: Federal Institute for Drugs and Medical Devices Japan: Pharmaceuticals and Medical Devices Agency Latvia: State Agency of Medicines Netherlands: Medicines Evaluation Board (MEB) Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Slovakia: State Institute for Drug Control Bulgaria: Bulgarian Drug Agency Korea: Food and Drug Administration