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Trial record **1 of 1** for: CQAB149B2335SE

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Safety, Tolerability and Efficacy of Indacaterol in Patients With Moderate-to-severe Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00677807

First received: May 13, 2008
Last updated: August 18, 2011
Last verified: August 2011
History of Changes

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Results First Received: July 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	COPD
Interventions:	Drug: Indacaterol Drug: Placebo

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
This is an extension study to core study stage 2: CQAB149B2335S (NCT00463567).

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 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Participant Flow: Overall Study

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo
STARTED	**144**	**146**	**125**
Safety/ITT: Received Study Drug	**144**	**146**	**124** [1]
COMPLETED	**126**	**135**	**105**
NOT COMPLETED	**18**	**11**	**20**

Adverse Event	**4**	**1**	**6**
Lack of Efficacy	**0**	**0**	**2**
Participant no longer needs study drug	**0**	**0**	**1**
Withdrawal by Subject	**10**	**3**	**6**
Lost to Follow-up	**2**	**2**	**2**
Administrative problems	**1**	**1**	**2**
Death	**0**	**1**	**1**
Protocol Deviation	**1**	**3**	**0**

[1] One patient did not take study medication.

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 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Total	Total of all reporting groups

Baseline Measures

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo	Total
Number of Participants [units: participants]	**144**	**146**	**124**	**414**
Age [1] [units: years] Mean (Standard Deviation)	**62.5 (9.52)**	**62.5 (9.00)**	**62.8 (9.18)**	**62.6 (9.21)**
Gender [units: participants]				
Female	**57**	**60**	**43**	**160**
Male	**87**	**86**	**81**	**254**

[1] All Baseline Measures were based on the safety population consisting of all participants who received at least one dose of study drug in the extension study.

Outcome Measures

Hide All Outcome Measures

1. Primary: The Number of Participants With a Clinically Notable Pulse Rate During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo [Time Frame: Up to 52 weeks]

Measure Type	Primary
Measure Title	The Number of Participants With a Clinically Notable Pulse Rate During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo
Measure Description	The number of participants with newly occurring or worsening clinically notable vital sign: Pulse Rate in beats per minute (bpm) at anytime post baseline (BL) by treatment.

	Low Pulse Rate was defined as a pulse rate: <40 bpm or <= to 50 bpm and a decrease from baseline >= to 15 bpm. High Pulse Rate was defined as a pulse rate: >130 bpm or >= to 120 bpm and an increase from baseline >= to 15 bpm.
Time Frame	Up to 52 weeks
Safety Issue	Yes

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.
Extension safety population consisting of all participants who received at least one dose of study drug in the extension study.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	**Indacaterol 300 µg**	**Placebo**
Number of Participants Analyzed **[units: participants]**	**144**	**146**	**124**
The Number of Participants With a Clinically Notable Pulse Rate During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo **[units: Participants]**			

Low Pulse Rate	**3**	**3**	**2**
High Pulse Rate	**0**	**1**	**0**

No statistical analysis provided for The Number of Participants With a Clinically Notable Pulse Rate During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo

2. Primary: The Number of Participants With a Clinically Notable Systolic Blood Pressure During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo [Time Frame: Up to 52 weeks]

Measure Type	Primary
Measure Title	The Number of Participants With a Clinically Notable Systolic Blood Pressure During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo
Measure Description	The number of participants with newly occurring or worsening clinically notable vital sign: Systolic Blood Pressure (mmHg) at anytime post baseline (BL) by treatment. A Low Systolic Blood Pressure was defined as a systolic blood pressure measurement: <75 mmHg or <= to 90 mmHg and a decrease from baseline >= to 20 mmHg. A High Systolic Blood Pressure was defined as a systolic blood pressure measurement: >200 mmHg or >= to 180 mmHg and an increase from baseline >= to 20 mmHg.
Time Frame	Up to 52 weeks
Safety Issue	Yes

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.
Extension safety population consisting of all participants who received at least one dose of study drug in the extension study.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**144**	**146**	**124**
The Number of Participants With a Clinically Notable Systolic Blood Pressure During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo [units: participants]			
Low Systolic Blood Pressure	**2**	**2**	**2**
High Systolic Blood Pressure	**1**	**2**	**2**

No statistical analysis provided for The Number of Participants With a Clinically Notable Systolic Blood Pressure During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo

3. Primary: The Number of Participants With a Clinically Notable Diastolic Blood Pressure During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo [Time Frame: Up to 52 weeks]

Measure Type	Primary
	The Number of Participants With a Clinically Notable Diastolic Blood Pressure During 52 Weeks of Treatment With

Measure Title	Indacaterol 150 µg or 300 µg Compared to Placebo
Measure Description	The number of participants with newly occurring or worsening clinically notable vital sign: Diastolic Blood Pressure (mmHg) at anytime post baseline (BL) by treatment. A Low Diastolic Blood Pressure was defined as a diastolic blood pressure measurement: <40 mmHg or <= to 50 mmHg and a decrease from baseline >= to 15 mmHg. A High Diastolic Blood Pressure was defined as a diastolic blood pressure measurement: >115 mmHg or >= to 105 mmHg and an increase from baseline >= to 15 mmHg.
Time Frame	Up to 52 weeks
Safety Issue	Yes

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.
Extension safety population consisting of all participants who received at least one dose of study drug in the extension study.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	**Indacaterol 300 µg**	**Placebo**

Number of Participants Analyzed [units: participants]	**144**	**146**	**124**
The Number of Participants With a Clinically Notable Diastolic Blood Pressure During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo [units: participants]			
Low Diastolic Blood Pressure	**6**	**3**	**2**
High Diastolic Blood Pressure	**1**	**0**	**2**

No statistical analysis provided for The Number of Participants With a Clinically Notable Diastolic Blood Pressure During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo

4. Primary: The Number of Participants With a Clinically Notable QTc Interval Value During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo [Time Frame: Up to 52 weeks]

Measure Type	Primary
Measure Title	The Number of Participants With a Clinically Notable QTc Interval Value During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo
Measure Description	The number of participants with newly occurring or worsening clinically notable QTc Interval value at anytime post baseline. The QTc interval is calculated using Fridericia's formula: QTc= QT/cube root RR. QTc is the interval between the Q and T waves corrected for heart rate and RR is the interval between two R waves in milliseconds (ms). Notable QTC interval= >450 ms for males and >470 ms for females. The maximum QTC increase from pre to post dose at any time during the study was also tabulated with absolute and relative frequencies for categories 30- 60 ms and >60 ms.
Time Frame	Up to 52 weeks
Safety Issue	Yes

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.
Extension safety population consisting of all participants who received at least one dose of study drug in the extension study.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**144**	**146**	**124**
The Number of Participants With a Clinically Notable QTc Interval Value During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo [units: participant]			
Notable QTc	**10**	**9**	**11**
QTc increase from BL: 30-60 ms	**28**	**30**	**30**
QTc increase from BL: >60 ms	**1**	**1**	**1**

No statistical analysis provided for The Number of Participants With a Clinically Notable QTc Interval Value During 52 Weeks of Treatment With Indacaterol 150 µg or 300 µg Compared to Placebo

5. Primary: Serum Potassium (mmol/L) 1 Hour Post-dose at Weeks 12, 26, 36, 44 and 52 [Time Frame: Weeks 12, 26, 36, 44 and 52]

Measure Type	Primary
Measure Title	Serum Potassium (mmol/L) 1 Hour Post-dose at Weeks 12, 26, 36, 44 and 52
Measure Description	The least squares mean of the serum potassium in mmol/L at weeks 12, 26, 36, 44 and 52. Mixed model used baseline serum potassium as a covariate.
Time Frame	Weeks 12, 26, 36, 44 and 52
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.
Extension safety population consisting of all participants who received at least one dose of study drug in the extension study. "n" in the categories is the number of participants with data at the given time point for each treatment.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	**Indacaterol 300 µg**	**Placebo**

Number of Participants Analyzed [units: participants]	**144**	**146**	**124**
Serum Potassium (mmol/L) 1 Hour Post-dose at Weeks 12, 26, 36, 44 and 52 [units: mmol/L] Least Squares Mean (Standard Error)			
Week 12 (n=140, 138, 115)	**4.45 (0.045)**	**4.50 (0.044)**	**4.45 (0.050)**
Week 26 (n=135, 141, 114)	**4.53 (0.049)**	**4.53 (0.047)**	**4.55 (0.053)**
Week 36 (n=132, 133, 109)	**4.46 (0.051)**	**4.49 (0.050)**	**4.55 (0.057)**
Week 44 (n=129, 130, 103)	**4.52 (0.050)**	**4.51 (0.048)**	**4.55 (0.055)**
Week 52 (n=121, 129, 97)	**4.42 (0.053)**	**4.54 (0.050)**	**4.49 (0.059)**

No statistical analysis provided for Serum Potassium (mmol/L) 1 Hour Post-dose at Weeks 12, 26, 36, 44 and 52

6. Primary: Blood Glucose (mmol/L) 1 Hour Post Dose at Weeks 12, 26, 36, 44 and 52 [Time Frame: Weeks 12, 26, 36, 44 and 52]

Measure Type	Primary
Measure Title	Blood Glucose (mmol/L) 1 Hour Post Dose at Weeks 12, 26, 36, 44 and 52
Measure Description	The least squares mean of the blood glucose in mmol/L at weeks 12, 26, 36, 44 and 52. Mixed model used baseline blood glucose as a covariate.
Time Frame	Weeks 12, 26, 36, 44 and 52
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.
Extension safety population consisting of all participants who received at least one dose of study drug in the extension study. "n" in the

categories is the number of participants with data at the given time point for each treatment.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**144**	**146**	**124**
Blood Glucose (mmol/L) 1 Hour Post Dose at Weeks 12, 26, 36, 44 and 52 [units: mmol/L] Least Squares Mean (Standard Error)			
Week 12 (n=142, 140, 118)	**5.50 (0.139)**	**5.59 (0.134)**	**5.18 (0.150)**
Week 26 (n=137, 143, 118)	**5.93 (0.169)**	**5.77 (0.160)**	**5.49 (0.180)**
Week 36 (n=134, 136, 111)	**5.81 (0.156)**	**5.75 (0.151)**	**5.66 (0.171)**
Week 44 (n=131, 133, 105)	**5.70 (0.189)**	**5.88 (0.176)**	**5.60 (0.205)**
Week 52 (n=123, 131, 99)	**5.93 (0.201)**	**5.70 (0.189)**	**5.55 (0.221)**

No statistical analysis provided for Blood Glucose (mmol/L) 1 Hour Post Dose at Weeks 12, 26, 36, 44 and 52

7. Secondary: Trough Forced Expiratory Volume in 1 Second (FEV1) at Week 52 of Treatment [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) at Week 52 of Treatment
Measure Description	Spirometry was conducted according to internationally accepted standards. The trough FEV1 was defined as the average of the FEV1 measurements taken at 23 hours 10 minutes and 23 hours 45 minutes post dose at week 52. The mixed model used baseline FEV1 as well as FEV1 reversibility components as covariates.
Time Frame	Week 52
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.
Participants from the Extension Intent-to-treat population (consisting of all participants who received at least one dose of study drug) for whom data was available for this Outcome Measure. Missing data was imputed Last Observation Carried Forward.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	**Indacaterol 300 µg**	**Placebo**
Number of Participants Analyzed			

[units: participants]	**125**	**133**	**104**
Trough Forced Expiratory Volume in 1 Second (FEV1) at Week 52 of Treatment **[units: Liters]** **Least Squares Mean (Standard Error)**	**1.44 (0.034)**	**1.45 (0.032)**	**1.27 (0.037)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) at Week 52 of Treatment

8. Secondary: Quality of Life Assessment With St George's Respiratory Questionnaire (SGRQ) Total Score at Weeks 36, 44 and 52 [Time Frame: Weeks 36, 44 and 52]

Measure Type	Secondary
Measure Title	Quality of Life Assessment With St George's Respiratory Questionnaire (SGRQ) Total Score at Weeks 36, 44 and 52
Measure Description	The least squares mean of the SGRQ total score at weeks 36, 44 and 52. Mixed model used for analysis used baseline SGRQ total score as well as FEV1 reversibility components as covariates. SGRQ is a health related quality of life questionnaire consisting of 50 items in three domains: symptoms, activity and impacts. The total score is 0 to 100 with a higher score indicating poorer health. A difference from placebo of -4 in the least squares mean SGRQ total score is considered clinically relevant.
Time Frame	Weeks 36, 44 and 52
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.
Extension Intent-to-treat population consisting of all participants who received at least one dose of study drug. "n" in each of the categories is the number of participants with data at the given time point. Missing data were imputed using LOCF but not by more than 14 weeks and not by carrying forward scores within 4 weeks of treatment start.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**144**	**146**	**124**
Quality of Life Assessment With St George's Respiratory Questionnaire (SGRQ) Total Score at Weeks 36, 44 and 52 [units: Score on a Scale] Least Squares Mean (Standard Error)			
Week 36 (n=138, 137, 113)	**36.62 (1.767)**	**36.37 (1.695)**	**39.56 (1.913)**
Week 44 (n= 128, 133, 109)	**35.98 (1.883)**	**36.18 (1.739)**	**41.67 (2.001)**
Week 52 (n=126, 132, 104)	**35.97 (1.826)**	**37.49 (1.721)**	**39.19 (2.004)**

No statistical analysis provided for Quality of Life Assessment With St George's Respiratory Questionnaire (SGRQ) Total Score at Weeks 36, 44 and 52

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	26 weeks
Additional Description	Safety population consisting of all participants who received at least one dose of study drug in the extension study.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Serious Adverse Events

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo
Total, serious adverse events			
# participants affected / at risk	**15/144 (10.42%)**	**18/146 (12.33%)**	**13/124 (10.48%)**
Cardiac disorders			
Acute myocardial infarction † [1]			
# participants affected / at risk	**0/144 (0.00%)**	**0/146 (0.00%)**	**1/124 (0.81%)**
Angina pectoris † [1]			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Atrial fibrillation † [1]			
# participants affected / at risk	**1/144 (0.69%)**	**0/146 (0.00%)**	**0/124 (0.00%)**

Cardiovascular disorder † 1			
# participants affected / at risk	**0/144 (0.00%)**	**0/146 (0.00%)**	**1/124 (0.81%)**
Coronary artery disease † 1			
# participants affected / at risk	**0/144 (0.00%)**	**0/146 (0.00%)**	**1/124 (0.81%)**
Myocardial infarction † 1			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**1/124 (0.81%)**
Sick sinus syndrome † 1			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Congenital, familial and genetic disorders			
Endocardial fibroelastosis † 1			
# participants affected / at risk	**0/144 (0.00%)**	**0/146 (0.00%)**	**1/124 (0.81%)**
Eye disorders			
Cataract † 1			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Gastrointestinal disorders			
Faecaloma † 1			
# participants affected / at risk	**0/144 (0.00%)**	**0/146 (0.00%)**	**1/124 (0.81%)**
Pancreatitis acute † 1			
# participants affected / at risk	**1/144 (0.69%)**	**0/146 (0.00%)**	**0/124 (0.00%)**
Rectal haemorrhage † 1			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Small intestinal obstruction † 1			
# participants affected / at risk	**1/144 (0.69%)**	**0/146 (0.00%)**	**0/124 (0.00%)**
General disorders			
Chest discomfort † 1			

# participants affected / at risk	0/144 (0.00%)	0/146 (0.00%)	1/124 (0.81%)
Hepatobiliary disorders			
Cholelithiasis † [1]			
# participants affected / at risk	0/144 (0.00%)	1/146 (0.68%)	0/124 (0.00%)
Infections and infestations			
Appendicitis † [1]			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Appendicitis perforated † [1]			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Infection † [1]			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Lobar pneumonia † [1]			
# participants affected / at risk	0/144 (0.00%)	0/146 (0.00%)	1/124 (0.81%)
Lower respiratory tract infection † [1]			
# participants affected / at risk	0/144 (0.00%)	1/146 (0.68%)	1/124 (0.81%)
Pelvic abscess † [1]			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Pneumonia † [1]			
# participants affected / at risk	0/144 (0.00%)	1/146 (0.68%)	0/124 (0.00%)
Sinusitis † [1]			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Upper respiratory tract infection † [1]			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Injury, poisoning and procedural complications			
Accidental overdose † [1]			

# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Fall † 1			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Femoral neck fracture † 1			
# participants affected / at risk	0/144 (0.00%)	0/146 (0.00%)	2/124 (1.61%)
Femur fracture † 1			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Foot fracture † 1			
# participants affected / at risk	0/144 (0.00%)	1/146 (0.68%)	0/124 (0.00%)
Hip fracture † 1			
# participants affected / at risk	0/144 (0.00%)	1/146 (0.68%)	0/124 (0.00%)
Road traffic accident † 1			
# participants affected / at risk	0/144 (0.00%)	1/146 (0.68%)	0/124 (0.00%)
Metabolism and nutrition disorders			
Diabetes mellitus † 1			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Musculoskeletal and connective tissue disorders			
Osteonecrosis † 1			
# participants affected / at risk	0/144 (0.00%)	1/146 (0.68%)	0/124 (0.00%)
Rotator cuff syndrome † 1			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer † 1			
# participants affected / at risk	1/144 (0.69%)	0/146 (0.00%)	0/124 (0.00%)
Colon cancer † 1			

# participants affected / at risk	**0/144 (0.00%)**	**0/146 (0.00%)**	**1/124 (0.81%)**
Lipoma † 1			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Nervous system disorders			
Cerebellar infarction † 1			
# participants affected / at risk	**0/144 (0.00%)**	**0/146 (0.00%)**	**1/124 (0.81%)**
Syncope † 1			
# participants affected / at risk	**1/144 (0.69%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	**4/144 (2.78%)**	**5/146 (3.42%)**	**3/124 (2.42%)**
Laryngeal leukoplakia † 1			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Pulmonary calcification † 1			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Vascular disorders			
Intermittent claudication † 1			
# participants affected / at risk	**0/144 (0.00%)**	**1/146 (0.68%)**	**0/124 (0.00%)**
Orthostatic hypotension † 1			
# participants affected / at risk	**1/144 (0.69%)**	**0/146 (0.00%)**	**0/124 (0.00%)**
Peripheral vascular disorder † 1			
# participants affected / at risk	**1/144 (0.69%)**	**0/146 (0.00%)**	**0/124 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	26 weeks
Additional Description	Safety population consisting of all participants who received at least one dose of study drug in the extension study.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once-daily (o.d.) via single-dose dry-powder inhaler (SDDPI). The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Indacaterol 300 µg once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo once-daily (o.d.) via SDDPI. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Other Adverse Events

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**86/144 (59.72%)**	**91/146 (62.33%)**	**67/124 (54.03%)**
Gastrointestinal disorders			
Diarrhoea † [1]			
# participants affected / at risk	**5/144 (3.47%)**	**5/146 (3.42%)**	**7/124 (5.65%)**
Nausea † [1]			

# participants affected / at risk	4/144 (2.78%)	6/146 (4.11%)	7/124 (5.65%)
Infections and infestations			
Bronchitis † [1]			
# participants affected / at risk	5/144 (3.47%)	9/146 (6.16%)	9/124 (7.26%)
Influenza † [1]			
# participants affected / at risk	8/144 (5.56%)	5/146 (3.42%)	3/124 (2.42%)
Lower respiratory tract infection † [1]			
# participants affected / at risk	5/144 (3.47%)	11/146 (7.53%)	8/124 (6.45%)
Nasopharyngitis † [1]			
# participants affected / at risk	24/144 (16.67%)	26/146 (17.81%)	19/124 (15.32%)
Sinusitis † [1]			
# participants affected / at risk	9/144 (6.25%)	11/146 (7.53%)	3/124 (2.42%)
Upper respiratory tract infection † [1]			
# participants affected / at risk	17/144 (11.81%)	20/146 (13.70%)	10/124 (8.06%)
Urinary tract infection † [1]			
# participants affected / at risk	5/144 (3.47%)	8/146 (5.48%)	4/124 (3.23%)
Musculoskeletal and connective tissue disorders			
Arthralgia † [1]			
# participants affected / at risk	5/144 (3.47%)	8/146 (5.48%)	1/124 (0.81%)
Back pain † [1]			
# participants affected / at risk	4/144 (2.78%)	4/146 (2.74%)	7/124 (5.65%)
Muscle spasms † [1]			
# participants affected / at risk	12/144 (8.33%)	4/146 (2.74%)	2/124 (1.61%)
Musculoskeletal pain † [1]			
# participants affected / at risk	5/144 (3.47%)	8/146 (5.48%)	1/124 (0.81%)

Nervous system disorders			
Headache † 1			
# participants affected / at risk	**15/144 (10.42%)**	**7/146 (4.79%)**	**5/124 (4.03%)**
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	**34/144 (23.61%)**	**36/146 (24.66%)**	**33/124 (26.61%)**
Cough † 1			
# participants affected / at risk	**17/144 (11.81%)**	**15/146 (10.27%)**	**8/124 (6.45%)**
Dyspnoea † 1			
# participants affected / at risk	**9/144 (6.25%)**	**4/146 (2.74%)**	**6/124 (4.84%)**
Oropharyngeal pain † 1			
# participants affected / at risk	**10/144 (6.94%)**	**10/146 (6.85%)**	**2/124 (1.61%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**6/144 (4.17%)**	**3/146 (2.05%)**	**7/124 (5.65%)**

† 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: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Chapman KR, Rennard SI, Dogra A, Owen R, Lassen C, Kramer B; INDORSE Study Investigators. Long-term safety and efficacy of indacaterol, a long-acting β_2-agonist, in subjects with COPD: a randomized, placebo-controlled study. Chest. 2011 Jul;140(1):68-75. doi: 10.1378/chest.10-

1830. Epub 2011 Feb 24.

Responsible Party:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00677807 History of Changes
Other Study ID Numbers:	**CQAB149B2335SE**
	2008-000663-42 (EudraCT Number)
Study First Received:	May 13, 2008
Results First Received:	July 22, 2011
Last Updated:	August 18, 2011
Health Authority:	United States: Food and Drug Administration
	Germany: Federal Institute for Drugs and Medical Devices
	Canada: Health Canada
	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica
	India: Institutional Review Board
	Italy: The Italian Medicines Agency
	Spain: Spanish Agency of Medicines
	Sweden: Medical Products Agency
	Turkey: Ministry of Health