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Trial record **1 of 1** for: CQAB149D2301

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Efficacy, Safety, Tolerability, and Pharmacokinetics of Indacaterol Salts in Patients With Asthma

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
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History of Changes

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Results First Received: July 29, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Asthma
Interventions:	Drug: Indacaterol maleate 400 µg Drug: Indacaterol acetate 400 µg Drug: Indacaterol xinafoate 400 µg Drug: Placebo to indacaterol

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 (Ind) Maleate-placebo-ind Xinafoate-ind Acetate	In treatment period 1, patients received indacaterol maleate 400 µg; in treatment period 2, patients received placebo to indacaterol; in treatment period 3, patients received indacaterol xinafoate 400 µg; and in treatment period 4, patients received indacaterol acetate 400 µg. Patients received each treatment for 7 days via the Concept1 single-dose dry-powder inhaler. There was a washout period of at least 7 days between each treatment period. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol (Ind) Xinafoate-ind Maleate-ind Acetate-placebo	In treatment period 1, patients received indacaterol xinafoate 400 µg; in treatment period 2, patients received indacaterol maleate 400 µg; in treatment period 3, patients received indacaterol acetate 400 µg; and in treatment period 4, patients received placebo to indacaterol 400 µg. Patients received each treatment for 7 days via the Concept1 single-dose dry-powder inhaler. There was a washout period of at least 7 days between each treatment period. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Indacaterol (Ind) Acetate-ind Xinafoate-placebo-ind Maleate	In treatment period 1, patients received indacaterol acetate 400 µg; in treatment period 2, patients received indacaterol xinafoate 400 µg; in treatment period 3, patients received placebo to indacaterol; and in treatment period 4, patients received indacaterol maleate 400 µg. Patients received each treatment for 7 days via the Concept1 single-dose dry-powder inhaler. There was a washout period of at least 7 days between each treatment period. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo-indacaterol (Ind) Acetate-ind Maleate-ind Xinafoate	In treatment period 1, patients received placebo to indacaterol; in treatment period 2, patients received indacaterol acetate 400 µg; in treatment period 3, patients received indacaterol maleate 400 µg; and in treatment period 4, patients received indacaterol xinafoate 400 µg. Patients received each treatment for 7 days via the Concept1 single-dose dry-powder inhaler. There was a washout period of at least 7 days between each treatment period. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Participant Flow for 4 periods

Period 1: Treatment Period 1

	Indacaterol (Ind) Maleate-placebo-ind Xinafoate-ind Acetate	Indacaterol (Ind) Xinafoate-ind Maleate-ind Acetate-placebo	Indacaterol (Ind) Acetate-ind Xinafoate-placebo-ind Maleate	Placebo-indacaterol (Ind) Acetate-ind Maleate-ind Xinafoate
STARTED	7	7	7	9
COMPLETED	7	7	6	9
NOT COMPLETED	0	0	1	0
Subject withdrew consent	0	0	1	0

Period 2: Treatment Period 2

	Indacaterol (Ind) Maleate-placebo-ind Xinafoate-ind Acetate	Indacaterol (Ind) Xinafoate-ind Maleate-ind Acetate-placebo	Indacaterol (Ind) Acetate-ind Xinafoate-placebo-ind Maleate	Placebo-indacaterol (Ind) Acetate-ind Maleate-ind Xinafoate
STARTED	7	7	6	9
COMPLETED	7	7	6	9
NOT COMPLETED	0	0	0	0

Period 3: Treatment Period 3

	Indacaterol (Ind) Maleate-placebo-ind Xinafoate-ind Acetate	Indacaterol (Ind) Xinafoate-ind Maleate-ind Acetate-placebo	Indacaterol (Ind) Acetate-ind Xinafoate-placebo-ind Maleate	Placebo-indacaterol (Ind) Acetate-ind Maleate-ind Xinafoate
STARTED	7	7	6	9
COMPLETED	7	7	6	9
NOT COMPLETED	0	0	0	0

Period 4: Treatment Period 4

	Indacaterol (Ind) Maleate-placebo-ind Xinafoate-ind Acetate	Indacaterol (Ind) Xinafoate-ind Maleate-ind Acetate-placebo	Indacaterol (Ind) Acetate-ind Xinafoate-placebo-ind Maleate	Placebo-indacaterol (Ind) Acetate-ind Maleate-ind Xinafoate
STARTED	7	7	6	9
COMPLETED	7	7	5	8

NOT COMPLETED	**0**	**0**	**1**	**1**
Adverse Event	**0**	**0**	**0**	**1**
Subject withdrew consent	**0**	**0**	**1**	**0**

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
Entire Study Population	The entire study population included all 4 treatment groups who received the 3 salt forms of indacaterol 400 µg (maleate, acetate, and xinafoate) and placebo to indacaterol in 4 different sequences. The dose refers to 400 µg of free base indacaterol. Patients received each treatment for 7 days via the Concept1 single-dose dry-powder inhaler. There was a washout period of at least 7 days between each treatment period. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Baseline Measures

	Entire Study Population

Number of Participants [units: participants]	**30**
Age [units: years] Mean (Standard Deviation)	**50 (12.3)**
Gender [units: participants]	
Female	**7**
Male	**23**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of Each Treatment Period (Day 7) [Time Frame: Baseline to the end of each treatment period (Day 7)]

Measure Type	Primary
Measure Title	Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of Each Treatment Period (Day 7)
Measure Description	FEV1 was measured with 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 at Baseline and at the end of each treatment period. The analysis included period baseline FEV1 as covariate.
Time Frame	Baseline to the end of each treatment period (Day 7)
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.

Efficacy analysis set: All randomized subjects that received at least 1 dose of study drug and had a baseline and at least 1 post-baseline measurement of FEV1.

Reporting Groups

	Description
Indacaterol Maleate 400 µg	Patients received indacaterol maleate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Acetate 400 µg	Patients received indacaterol acetate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Xinafoate 400 µg	Patients received indacaterol xinafoate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol once daily for 7 days via the Concept1 single-dose dry-powder inhaler. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol Maleate 400 µg	Indacaterol Acetate 400 µg	Indacaterol Xinafoate 400 µg	Placebo to Indacaterol
Number of Participants Analyzed [units: participants]	**28**	**29**	**28**	**29**
Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of Each Treatment Period (Day 7) [units: Liters]	**0.186 (0.1079 to 0.2649)**	**0.190 (0.1133 to 0.2673)**	**0.194 (0.1164 to 0.2728)**	**-0.021 (-0.0982 to 0.0558)**

Least Squares Mean (90% Confidence Interval)				

No statistical analysis provided for Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of Each Treatment Period (Day 7)

2. Secondary: Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose on Day 1 [Time Frame: Baseline to Day 1]

Measure Type	Secondary
Measure Title	Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose on Day 1
Measure Description	FEV1 was measured with 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 at Baseline and on Day 1. The analysis included period baseline FEV1 as covariate.
Time Frame	Baseline to Day 1
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.
Efficacy analysis set: All randomized subjects that received at least 1 dose of study drug and had a baseline and at least 1 post-baseline measurement of FEV1.

Reporting Groups

	Description
Indacaterol Maleate 400 µg	Patients received indacaterol maleate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Indacaterol Acetate 400 µg	Patients received indacaterol acetate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Xinafoate 400 µg	Patients received indacaterol xinafoate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol once daily for 7 days via the Concept1 single-dose dry-powder inhaler. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol Maleate 400 µg	**Indacaterol Acetate 400 µg**	**Indacaterol Xinafoate 400 µg**	**Placebo to Indacaterol**
Number of Participants Analyzed [units: participants]	**29**	**30**	**29**	**29**
Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose on Day 1 [units: Liters] Least Squares Mean (90% Confidence Interval)	**0.161 (0.0877 to 0.2344)**	**0.185 (0.1129 to 0.2572)**	**0.205 (0.1325 to 0.2792)**	**0.008 (-0.0649 to 0.0819)**

No statistical analysis provided for Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose on Day 1

3. Secondary: Time to Peak Forced Expiratory Volume in 1 Second (FEV1) on Day 1 and Day 7 [Time Frame: Day 1 and Day 7]

Measure Type	Secondary
Measure Title	Time to Peak Forced Expiratory Volume in 1 Second (FEV1) on Day 1 and Day 7

Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards at 5, 15, and 30 minutes; 1 hour, 1 hour 30 minutes; and 2, 4, and 12 hours post-dose on Day 1 and Day 7.
Time Frame	Day 1 and Day 7
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.
Efficacy analysis set: All randomized subjects that received at least 1 dose of study drug and had a baseline and at least 1 post-baseline measurement of FEV1.

Reporting Groups

	Description
Indacaterol Maleate 400 µg	Patients received indacaterol maleate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Acetate 400 µg	Patients received indacaterol acetate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Xinafoate 400 µg	Patients received indacaterol xinafoate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol once daily for 7 days via the Concept1 single-dose dry-powder inhaler. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol Maleate 400 µg	Indacaterol Acetate 400 µg	Indacaterol Xinafoate 400 µg	Placebo to Indacaterol
Number of Participants Analyzed [units: participants]	**29**	**30**	**29**	**29**
Time to Peak Forced Expiratory Volume in 1 Second (FEV1) on Day 1 and Day 7 [units: Hours] Median (90% Confidence Interval)				
Day 1, N=29, 30, 29, 29	**4.00 (3.000 to 6.125)**	**2.13 (1.500 to 3.000)**	**1.50 (1.040 to 2.500)**	**2.25 (1.500 to 12.085)**
Day 7, N=28, 29, 28, 29	**3.00 (2.000 to 4.000)**	**2.50 (1.500 to 4.000)**	**3.00 (1.250 to 12.000)**	**12.38 (11.710 to 13.875)**

No statistical analysis provided for Time to Peak Forced Expiratory Volume in 1 Second (FEV1) on Day 1 and Day 7

4. Secondary: Percentage of Patients Using Rescue Medication During Each 7 Day Treatment Period [Time Frame: Baseline to the end of each treatment period (Day 7)]

Measure Type	Secondary
Measure Title	Percentage of Patients Using Rescue Medication During Each 7 Day Treatment Period
Measure Description	Patients recorded use of rescue medication (salbutamol/albuterol multi-dose inhaler) as the number of puffs taken in respective preceding 12 hours morning and evening in a diary. Patient with any use of rescue medication (any number of puffs > 0) was included to calculate endpoint.
Time Frame	Baseline to the end of each treatment period (Day 7)
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.
Efficacy analysis set: All randomized subjects that received at least 1 dose of study drug and had a baseline and at least 1 post-baseline measurement of FEV1.

Reporting Groups

	Description
Indacaterol Maleate 400 µg	Patients received indacaterol maleate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Acetate 400 µg	3Patients received indacaterol acetate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Xinafoate 400 µg	Patients received indacaterol xinafoate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol once daily for 7 days via the Concept1 single-dose dry-powder inhaler. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol Maleate 400 µg	**Indacaterol Acetate 400 µg**	**Indacaterol Xinafoate 400 µg**	**Placebo to Indacaterol**
Number of Participants Analyzed [units: participants]	**29**	**30**	**29**	**29**

Percentage of Patients Using Rescue Medication During Each 7 Day Treatment Period [units: Percentage of participants]	**21**	**10**	**17**	**21**

No statistical analysis provided for Percentage of Patients Using Rescue Medication During Each 7 Day Treatment Period

5. Secondary: Indacaterol Exposure (AUC[0-24 Hours]) at the End of Each 7 Day Treatment Period [Time Frame: End of each treatment period (Day 7)]

Measure Type	Secondary
Measure Title	Indacaterol Exposure (AUC[0-24 Hours]) at the End of Each 7 Day Treatment Period
Measure Description	Venous blood samples for pharmacokinetic evaluation were collected at 15 and 30 minutes; and 1, 2, 4, 12, and 24 hours post-dose at the end of each 7 day treatment period and were analyzed using a LC-MS/MS assay. Area under the concentration-time curve up to 24 hours (AUC[0-24 hours]) was calculated from concentration-time data and recorded sampling times using non-compartmental methods.
Time Frame	End of each treatment period (Day 7)
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 analysis set: All subjects with evaluable pharmacokinetic parameter data. Number of subjects varied due to missing values.

Reporting Groups

	Description
Indacaterol Acetate 400 µg	Patients received indacaterol acetate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Indacaterol Maleate 400 µg	Patients received indacaterol maleate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Xinafoate 400 µg	Patients received indacaterol xinafoate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol Acetate 400 µg	**Indacaterol Maleate 400 µg**	**Indacaterol Xinafoate 400 µg**
Number of Participants Analyzed [units: participants]	**29**	**28**	**27**
Indacaterol Exposure (AUC[0-24 Hours]) at the End of Each 7 Day Treatment Period [units: pg * hr/mL] Geometric Mean (Geometric Coefficient of Variation)	**5159 (3003% to 10893%)**	**5434 (3581% to 13634%)**	**5170 (3312% to 8349%)**

No statistical analysis provided for Indacaterol Exposure (AUC[0-24 Hours]) at the End of Each 7 Day Treatment Period

6. Secondary: Indacaterol Exposure (Cmax) at the End of Each 7 Day Treatment Period [Time Frame: End of each treatment period (Day 7)]

Measure Type	Secondary
Measure Title	Indacaterol Exposure (Cmax) at the End of Each 7 Day Treatment Period
Measure Description	Venous blood samples for pharmacokinetic evaluation were collected at 15 and 30 minutes; and 1, 2, 4, 12, and 24 hours post-dose at the end of each 7 day treatment period and were analyzed using a LC-MS/MS assay. Maximum (peak) plasma drug concentration after drug administration (Cmax) was calculated from concentration-time data and recorded sampling times using non-compartmental methods.

Time Frame	End of each treatment period (Day 7)
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 analysis set: All subjects with evaluable pharmacokinetic parameter data. Number of subjects varied due to missing values.

Reporting Groups

	Description
Indacaterol Acetate 400 µg	Patients received indacaterol acetate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Maleate 400 µg	Patients received indacaterol maleate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Xinafoate 400 µg	Patients received indacaterol xinafoate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol Acetate 400 µg	**Indacaterol Maleate 400 µg**	**Indacaterol Xinafoate 400 µg**
Number of Participants Analyzed [units: participants]	**28**	**28**	**28**
Indacaterol Exposure (Cmax) at the End of Each 7 Day Treatment Period	**720 (338% to 1550%)**	**753 (322% to 1870%)**	

[units: pg/mL] Geometric Mean (Geometric Coefficient of Variation)			**664 (397% to 1150%)**

No statistical analysis provided for Indacaterol Exposure (Cmax) at the End of Each 7 Day Treatment Period

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Baseline to the end of the study (approximately 11 weeks)
Additional Description	Safety population: All subjects who received at least 1 dose of study drug.

Reporting Groups

	Description
Indacaterol Acetate 400 µg	Patients received indacaterol acetate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Maleate 400 µg	Patients received indacaterol maleate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Xinafoate 400 µg	Patients received indacaterol xinafoate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol once daily for 7 days via the Concept1 single-dose dry-powder inhaler. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Serious Adverse Events

	Indacaterol Acetate 400 µg	Indacaterol Maleate 400 µg	Indacaterol Xinafoate 400 µg	Placebo to Indacaterol
Total, serious adverse events				
# participants affected / at risk	**0/30 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Baseline to the end of the study (approximately 11 weeks)
Additional Description	Safety population: All subjects who received at least 1 dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol Acetate 400 µg	Patients received indacaterol acetate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol Maleate 400 µg	Patients received indacaterol maleate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Indacaterol Xinafoate 400 µg	Patients received indacaterol xinafoate 400 µg once daily for 7 days via the Concept1 single-dose dry-powder inhaler. The dose refers to 400 µg of free base indacaterol. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol once daily for 7 days via the Concept1 single-dose dry-powder inhaler. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Other Adverse Events

	Indacaterol Acetate 400 µg	Indacaterol Maleate 400 µg	Indacaterol Xinafoate 400 µg	Placebo to Indacaterol
Total, other (not including serious) adverse events				
# participants affected / at risk	**5/30 (16.67%)**	**4/29 (13.79%)**	**7/29 (24.14%)**	**5/29 (17.24%)**
Infections and infestations				
Nasopharyngitis † 1				
# participants affected / at risk	**0/30 (0.00%)**	**0/29 (0.00%)**	**4/29 (13.79%)**	**1/29 (3.45%)**
Nervous system disorders				
Headache † 1				
# participants affected / at risk	**1/30 (3.33%)**	**1/29 (3.45%)**	**2/29 (6.90%)**	**4/29 (13.79%)**
Respiratory, thoracic and mediastinal disorders				
Cough † 1				
# participants affected / at risk	**4/30 (13.33%)**	**3/29 (10.34%)**	**2/29 (6.90%)**	**0/29 (0.00%)**

† 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 (ie, 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

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00927901 History of Changes
Other Study ID Numbers:	**CQAB149D2301** 2009-010589-46 (EudraCT Number)
Study First Received:	June 24, 2009
Results First Received:	July 29, 2011
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