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Trial record **1 of 1** for: CQAB149B2222

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Efficacy, Safety, Tolerability, and Pharmacokinetics of Indacaterol Maleate Via Concept1 or Simoon Devices

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01012739

First received: November 12, 2009
Last updated: August 25, 2011
Last verified: August 2011
History of Changes

Results First Received: July 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Asthma
Interventions:	Drug: Indacaterol 150 µg via the Concept1 dry-powder inhaler Drug: Indacaterol 60 µg via the Simoon dry-powder inhaler Drug: Indacaterol 120 µg via the Simoon dry-powder inhaler Drug: Placebo to indacaterol via the Concept1 dry-powder inhaler

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 150µg-placebo-Indacaterol 60µg-Indacaterol 120µg	In treatment period 1, patients received indacaterol 150 µg via the Concept1 dry-powder inhaler (DPI); in treatment period 2, patients received placebo to indacaterol via the Concept1 DPI; in treatment period 3, patients received indacaterol 60 µg via the Simoon DPI; and in treatment period 4, patients received indacaterol 120 µg via the Simoon DPI. Patients received each treatment only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60µg-Indacaterol 150µg-Indacaterol 120µg-placebo	In treatment period 1, patients received indacaterol 60 µg via the Simoon dry-powder inhaler (DPI); in treatment period 2, patients received indacaterol 150 µg via the Concept1 DPI; in treatment period 3, patients received indacaterol 120 µg via the Simoon DPI; and in treatment period 4, patients received placebo to indacaterol via the Concept1 DPI. Patients received each treatment only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK)

	assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120µg-Indacaterol 60µg-placebo-Indacaterol 150µg	In treatment period 1, patients received indacaterol 120 µg via the Simoon dry-powder inhaler (DPI); in treatment period 2, patients received indacaterol 60 µg via the Simoon DPI; in treatment period 3, patients received placebo to indacaterol via the Concept1 DPI; and in treatment period 4, patients received indacaterol 150 µg via the Concept1 DPI. Patients received each treatment only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo-Indacaterol 120µg- Indacaterol 150µg- Indacaterol 60µg	In treatment period 1, patients received placebo to indacaterol via the Concept1 dry-powder inhaler (DPI); in treatment period 2, patients received indacaterol 120 µg via the Simoon DPI; in treatment period 3, patients received indacaterol 150 µg via the Concept1 DPI; and in treatment period 4, patients received indacaterol 60 µg via the Simoon DPI. Patients received each treatment only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Participant Flow for 4 periods

Period 1: Treatment Period 1

	Indacaterol 150µg-placebo-Indacaterol 60µg-Indacaterol 120µg	Indacaterol 60µg-Indacaterol 150µg-Indacaterol 120µg-placebo	Indacaterol 120µg-Indacaterol 60µg-placebo-Indacaterol 150µg	Placebo-Indacaterol 120µg-Indacaterol 150µg- Indacaterol 60µg
STARTED	**9**	**8**	**9**	**9**

COMPLETED	**9**	**8**	**9**	**8**
NOT COMPLETED	**0**	**0**	**0**	**1**
Adverse Event	**0**	**0**	**0**	**1**

Period 2: Treatment Period 2

	Indacaterol 150µg-placebo-Indacaterol 60µg-Indacaterol 120µg	Indacaterol 60µg-Indacaterol 150µg-Indacaterol 120µg-placebo	Indacaterol 120µg-Indacaterol 60µg-placebo-Indacaterol 150µg	Placebo-Indacaterol 120µg-Indacaterol 150µg-Indacaterol 60µg
STARTED	**9**	**8**	**9**	**8**
COMPLETED	**9**	**8**	**9**	**7**
NOT COMPLETED	**0**	**0**	**0**	**1**
Abnormal test procedure results	**0**	**0**	**0**	**1**

Period 3: Treatment Period 3

	Indacaterol 150µg-placebo-Indacaterol 60µg-Indacaterol 120µg	Indacaterol 60µg-Indacaterol 150µg-Indacaterol 120µg-placebo	Indacaterol 120µg-Indacaterol 60µg-placebo-Indacaterol 150µg	Placebo-Indacaterol 120µg-Indacaterol 150µg- Indacaterol 60µg
STARTED	**9**	**8**	**9**	**7**
COMPLETED	**9**	**8**	**9**	**7**
NOT COMPLETED	**0**	**0**	**0**	**0**

Period 4: Treatment Period 4

	Indacaterol 150µg-placebo-Indacaterol 60µg-Indacaterol 120µg	Indacaterol 60µg-Indacaterol 150µg-Indacaterol 120µg-placebo	Indacaterol 120µg-Indacaterol 60µg-placebo-Indacaterol 150µg	Placebo-Indacaterol 120µg-Indacaterol 150µg- Indacaterol 60µg
STARTED	**9**	**8**	**9**	**7**
COMPLETED	**9**	**8**	**9**	**7**
NOT COMPLETED	**0**	**0**	**0**	**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 indacaterol 150 µg via the Concept1 dry-powder inhaler (DPI), indacaterol 60 µg via the Simoon DPI, indacaterol 120 µg via the Simoon DPI, and placebo to indacaterol via the Concept1 DPI. Patients received each treatment only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for

	rescue use throughout the study.

Baseline Measures

	Entire Study Population
Number of Participants [units: participants]	**35**
Age [units: years] Mean (Standard Deviation)	**42.6 (11.42)**
Gender [units: participants]	
Female	**10**
Male	**25**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose for Each Treatment [Time Frame: Baseline and Day 1]

Measure Type	Primary
Measure Title	Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose for Each Treatment
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 for each treatment.
Time Frame	Baseline and 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.
Pharmacodynamic analysis set: All randomized patients 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 150 µg	Patients received indacaterol 150 µg via the Concept1 dry-powder inhaler (DPI) only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60 µg	Patients received Indacaterol 60 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120 µg	Patients received Indacaterol 120 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol via the Concept1 dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 60 µg	Indacaterol 120 µg	Placebo to Indacaterol
Number of Participants Analyzed [units: participants]	**33**	**33**	**34**	**35**
Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose for Each Treatment [units: Liters] Mean (Standard Deviation)	**2.97 (0.695)**	**2.93 (0.688)**	**2.91 (0.734)**	**2.77 (0.67)**

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

2. Secondary: Change From Baseline in Peak Forced Expiratory Volume in 1 Second (FEV1) for Each Treatment [Time Frame: Baseline and Day 1]

Measure Type	Secondary
Measure Title	Change From Baseline in Peak Forced Expiratory Volume in 1 Second (FEV1) for Each Treatment
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. Measurements were made at 5, 15, and 30 minutes; and 1, 2, 4, 6, 8, and 12 hours post-dose in Day 1.
Time Frame	Baseline and 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.
Pharmacodynamic analysis set: All randomized patients 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 150 µg	Patients received indacaterol 150 µg via the Concept1 dry-powder inhaler (DPI) only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60 µg	Patients received Indacaterol 60 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120 µg	Patients received Indacaterol 120 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol via the Concept1 dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 60 µg	Indacaterol 120 µg	Placebo to Indacaterol
Number of Participants Analyzed [units: participants]	**33**	**33**	**34**	**35**
Change From Baseline in Peak Forced Expiratory Volume in 1 Second (FEV1) for Each Treatment [units: Liters]	**3.19 (0.747)**	**3.15 (0.745)**	**3.15 (0.717)**	**2.96 (0.682)**

Mean (Standard Deviation)				

No statistical analysis provided for Change From Baseline in Peak Forced Expiratory Volume in 1 Second (FEV1) for Each Treatment

3. Secondary: Time to Peak Forced Expiratory Volume in 1 Second (FEV1) for Each Treatment [Time Frame: From 5 minutes to 12 hours post-dose]

Measure Type	Secondary
Measure Title	Time to Peak Forced Expiratory Volume in 1 Second (FEV1) for Each Treatment
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 1, 2, 4, 6, 8, and 12 hours post-dose in Day 1.
Time Frame	From 5 minutes to 12 hours post-dose
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.
Pharmacodynamic analysis set: All randomized patients 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 150 µg	Patients received indacaterol 150 µg via the Concept1 dry-powder inhaler (DPI) only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60 µg	Patients received Indacaterol 60 µg via the Simoon dry-powder inhaler only once. There was a washout period of

	14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120 µg	Patients received Indacaterol 120 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol via the Concept1 dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 60 µg	Indacaterol 120 µg	Placebo to Indacaterol
Number of Participants Analyzed [units: participants]	**33**	**33**	**34**	**35**
Time to Peak Forced Expiratory Volume in 1 Second (FEV1) for Each Treatment [units: Hours] Mean (Standard Deviation)	**6.80 (7.614)**	**8.22 (7.990)**	**7.50 (7.370)**	**7.93 (7.747)**

No statistical analysis provided for Time to Peak Forced Expiratory Volume in 1 Second (FEV1) for Each Treatment

4. Secondary: Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) From 5 Minutes to 4 Hours Post-dose for Each Treatment [Time Frame: From 5 minutes to 4 hours post-dose for each treatment]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) From 5 Minutes to 4 Hours Post-dose for Each Treatment
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. Measurements were made at 5, 15, and 30 minutes; and 1, 2, and 4 hours post-dose. The standardized AUC FEV1 was calculated as the sum of trapezoids divided by the length of time.
Time Frame	From 5 minutes to 4 hours post-dose for each treatment
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.
Pharmacodynamic analysis set: All randomized patients 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 150 µg	Patients received indacaterol 150 µg via the Concept1 dry-powder inhaler (DPI) only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60 µg	Patients received Indacaterol 60 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120 µg	Patients received Indacaterol 120 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if

	applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol via the Concept1 dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 60 µg	Indacaterol 120 µg	Placebo to Indacaterol
Number of Participants Analyzed [units: participants]	**33**	**33**	**34**	**35**
Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) From 5 Minutes to 4 Hours Post-dose for Each Treatment [units: Liters] Mean (Standard Deviation)	**3.03 (0.743)**	**2.96 (0.732)**	**2.99 (0.722)**	**2.78 (0.651)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) From 5 Minutes to 4 Hours Post-dose for Each Treatment

5. Secondary: Indacaterol Exposure (AUC[0-24 Hours]) for Each Treatment [Time Frame: 0 to 24 hours post-dose]

Measure Type	Secondary
Measure Title	Indacaterol Exposure (AUC[0-24 Hours]) for Each Treatment
Measure Description	All patients fasted for at least 10 hours prior to administration of study medication and continued to fast for at least 4 hours thereafter. Venous blood samples for pharmacokinetic evaluation were collected at 5, 10, 15, and 30 minutes;

	and 1, 2, 4, 8, and 24 hours post-dose in each 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 using non-compartmental analysis.
Time Frame	0 to 24 hours post-dose
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 randomized patients with evaluable pharmacokinetic data, ie, from which at least one pharmacokinetic parameter could be determined and sampling time information was available, from at least one treatment period.

Reporting Groups

	Description
Indacaterol 150 µg	Patients received Indacaterol 150 µg via the Concept1 dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60 µg	Patients received Indacaterol 60 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120 µg	Patients received Indacaterol 120 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	**Indacaterol 60 µg**	**Indacaterol 120 µg**
Number of Participants Analyzed			

[units: participants]	**15**	**14**	**14**
Indacaterol Exposure (AUC[0-24 Hours]) for Each Treatment [units: pg*hr/mL] Mean (Standard Deviation)	**1119.2 (379.1)**	**435.8 (245.7)**	**849.4 (272.7)**

No statistical analysis provided for Indacaterol Exposure (AUC[0-24 Hours]) for Each Treatment

6. Secondary: Indacaterol Exposure (Cmax) for Each Treatment [Time Frame: 0 to 24 hours post-dose]

Measure Type	Secondary
Measure Title	Indacaterol Exposure (Cmax) for Each Treatment
Measure Description	All patients fasted for at least 10 hours prior to administration of study medication and continued to fast for at least 4 hours thereafter. Venous blood samples for pharmacokinetic evaluation were collected at 5, 10, 15, and 30 minutes; and 1, 2, 4, 8, and 24 hours post-dose in each 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 using non-compartmental analysis.
Time Frame	0 to 24 hours post-dose
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 randomized patients with evaluable pharmacokinetic data, ie, from which at least one pharmacokinetic parameter could be determined and sampling time information was available, from at least one treatment period.

Reporting Groups

	Description

Indacaterol 150 µg	Patients received Indacaterol 150 µg via the Concept1 dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60 µg	Patients received Indacaterol 60 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120 µg	Patients received Indacaterol 120 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 60 µg	Indacaterol 120 µg
Number of Participants Analyzed [units: participants]	**15**	**14**	**14**
Indacaterol Exposure (Cmax) for Each Treatment [units: pg/mL] Mean (Standard Deviation)	**150.5 (30.4)**	**95.2 (57.3)**	**141.7 (55.0)**

No statistical analysis provided for Indacaterol Exposure (Cmax) for Each Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety population included all randomized patients that received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol 150 µg	Patients received indacaterol 150 µg via the Concept1 dry-powder inhaler (DPI)only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60 µg	Patients received Indacaterol 60 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120 µg	Patients received indacaterol 120 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol via the Concept1 dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Serious Adverse Events

	Indacaterol 150 µg	Indacaterol 60 µg	Indacaterol 120 µg	Placebo to Indacaterol
Total, serious adverse events				
# participants affected / at risk	**0/33 (0.00%)**	**0/33 (0.00%)**	**0/34 (0.00%)**	**0/35 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Safety population included all randomized patients that received at least one dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol 150 µg	Patients received indacaterol 150 µg via the Concept1 dry-powder inhaler (DPI)only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 60 µg	Patients received Indacaterol 60 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Indacaterol 120 µg	Patients received indacaterol 120 µg via the Simoon dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo to Indacaterol	Patients received placebo to indacaterol via the Concept1 dry-powder inhaler only once. There was a washout period of 14-17 days between treatments for patients undergoing pharmacokinetic (PK) assessments; for patients not undergoing PK assessments, the washout period was 7-10 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Other Adverse Events

	Indacaterol 150 µg	Indacaterol 60 µg	Indacaterol 120 µg	Placebo to Indacaterol
Total, other (not including serious) adverse events				
# participants affected / at risk	**19/33 (57.58%)**	**16/33 (48.48%)**	**21/34 (61.76%)**	**11/35 (31.43%)**
Infections and infestations				
Nasopharyngitis † 1				
# participants affected / at risk	**0/33 (0.00%)**	**0/33 (0.00%)**	**1/34 (2.94%)**	**2/35 (5.71%)**
Nervous system disorders				
Headache † 1				
# participants affected / at risk	**5/33 (15.15%)**	**4/33 (12.12%)**	**3/34 (8.82%)**	**3/35 (8.57%)**
Respiratory, thoracic and mediastinal disorders				
Cough † 1				
# participants affected / at risk	**16/33 (48.48%)**	**15/33 (45.45%)**	**19/34 (55.88%)**	**6/35 (17.14%)**

† 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:	NCT01012739 History of Changes
Other Study ID Numbers:	**CQAB149B2222**
	2009-012600-48 (EudraCT Number)
Study First Received:	November 12, 2009

Results First Received:	July 22, 2011
Last Updated:	August 25, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices United Kingdom: Medicines and Healthcare Products Regulatory Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)