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Trial record **1 of 1** for: CNVA237A2207

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A Study to Investigate the Bronchodilatory Effect of NVA237 in Patients With Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00856193

First received: March 4, 2009
Last updated: June 8, 2011
Last verified: June 2011
History of Changes

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Results First Received: January 20, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: Placebo Drug: NVA237

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
Patients were randomized into one of two sequences to receive either NVA237 50 µg followed by placebo or placebo followed by NVA237 50 µg.

Reporting Groups

	Description
NVA237 50µg Then Placebo	NVA237 50 µg capsules followed by matching placebo 50 µg capsules for inhalation once daily with Concept 1 device.
Placebo Then NVA237 50µg	Placebo 50 µg capsules followed by NVA237 50 µg capsules for inhalation once daily with Concept 1 device.

Participant Flow for 2 periods

Period 1: Period 1

	NVA237 50µg Then Placebo	Placebo Then NVA237 50µg
STARTED	16	17
COMPLETED	16	17
NOT COMPLETED	0	0

Period 2: Period 2

	NVA237 50µg Then Placebo	Placebo Then NVA237 50µg

STARTED	**16**	**17**
COMPLETED	**16**	**15**
NOT COMPLETED	**0**	**2**
Abnormal test procedure results	**0**	**1**
Lost to Follow-up	**0**	**1**

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
All Randomized Patients	NVA237 50 µg capsules for inhalation once daily with Concept 1 device. Matching placebo 50 µg capsules for inhalation once daily with Concept 1 device.

Baseline Measures

	All Randomized Patients
Number of Participants [units: participants]	**33**
Age [units: years] Mean (Standard Deviation)	**60.5 (9.13)**
Gender	

[units: participants]	
Female	11
Male	22

Outcome Measures

Hide All Outcome Measures

1. Primary: Forced Expiratory Volume in One Second (FEV1) Area Under Curve (AUC) 0-24 Hours on Day 14 [Time Frame: From Day 1 to 0-24 hours after drug administration on Day 14]

Measure Type	Primary
Measure Title	Forced Expiratory Volume in One Second (FEV1) Area Under Curve (AUC) 0-24 Hours on Day 14
Measure Description	Forced Expiratory Volume in one second (FEV1) was calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. This outcome measures the change is FEV1 from predose (day 1) to the readings taken 0-24 hours post dose on day 14. The variable was analyzed with an analysis-of-covariance model which included baseline FEV1 value as a covariate.
Time Frame	From Day 1 to 0-24 hours after drug administration on Day 14
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analysis set

Reporting Groups

	Description
NVA237 50µg	NVA237 50 µg capsules were supplied by Novartis for inhalation once daily with Concept 1 device.

Placebo	Matching placebo capsules were supplied by Novartis for inhalation once daily with Concept 1 device.

Measured Values

	NVA237 50µg	Placebo
Number of Participants Analyzed [units: participants]	**31**	**32**
Forced Expiratory Volume in One Second (FEV1) Area Under Curve (AUC) 0-24 Hours on Day 14 [units: Liters] Least Squares Mean (Standard Error)	**1.827 (0.0330)**	**1.664 (0.0324)**

No statistical analysis provided for Forced Expiratory Volume in One Second (FEV1) Area Under Curve (AUC) 0-24 Hours on Day 14

2. Secondary: Forced Expiratory Volume in One Second (FEV1) AUC 0-12 Hours on Day 14 [Time Frame: From day 1 to 0 -12 hours after drug administration on Day 14]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in One Second (FEV1) AUC 0-12 Hours on Day 14
Measure Description	Forced Expiratory Volume in one second (FEV1) was calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. This outcome measures the change is FEV1 from pre-dose (day 1) to the readings taken 0-12 hours post dose on day 14. The variable was analyzed with an analysis-of-covariance model which included baseline FEV1 value as a covariate.
Time Frame	From day 1 to 0 -12 hours after drug administration on Day 14
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Efficacy analysis set

Reporting Groups

	Description
NVA237 50µg	NVA237 50 µg capsules were supplied by Novartis for inhalation once daily with Concept 1 device.
Placebo	Matching placebo capsules were supplied by Novartis for inhalation once daily with Concept 1 device.

Measured Values

	NVA237 50µg	Placebo
Number of Participants Analyzed [units: participants]	**31**	**32**
Forced Expiratory Volume in One Second (FEV1) AUC 0-12 Hours on Day 14 [units: Liters] Least Squares Mean (Standard Error)	**1.879 (0.0346)**	**1.714 (0.0340)**

No statistical analysis provided for Forced Expiratory Volume in One Second (FEV1) AUC 0-12 Hours on Day 14

3. Secondary: Forced Expiratory Volume in One Second (FEV1) AUC 12-24 Hours on Day 14 [Time Frame: From Day 1 to 12 hours-24 hours after drug administration on Day 14]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in One Second (FEV1) AUC 12-24 Hours on Day 14
Measure Description	Forced Expiratory Volume in one second (FEV1) was calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. This outcome measures the change is FEV1 from pre-dose (day 1) to the readings taken 12-24 hours post dose on day 14. The variable was analyzed with an analysis-of-covariance model which included baseline FEV1 value as a covariate.
Time Frame	From Day 1 to 12 hours-24 hours after drug administration on Day 14

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analysis set

Reporting Groups

	Description
NVA237 50µg	NVA237 50 µg capsules were supplied by Novartis for inhalation once daily with Concept 1 device.
Placebo	Matching placebo capsules were supplied by Novartis for inhalation once daily with Concept 1 device.

Measured Values

	NVA237 50µg	**Placebo**
Number of Participants Analyzed [units: participants]	**31**	**32**
Forced Expiratory Volume in One Second (FEV1) AUC 12-24 Hours on Day 14 [units: Liters] Least Squares Mean (Standard Error)	**1.776 (0.0344)**	**1.615 (0.0339)**

No statistical analysis provided for Forced Expiratory Volume in One Second (FEV1) AUC 12-24 Hours on Day 14

4. Secondary: Number of Participants Who Experienced Adverse Events (AEs), Serious Adverse Events (SAEs) [Time Frame: Day 14]

Measure Type	Secondary
Measure Title	Number of Participants Who Experienced Adverse Events (AEs), Serious Adverse Events (SAEs)
Measure Description	According to FDA 21CFR 314.80, a serious adverse event (SAE) is described as any adverse event that leads to

	death, is life threatening , causes or prolongs hospitalization, results in a congenital anomaly, or any other important medical event not described above. See Adverse Events module for details.
Time Frame	Day 14
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.
Safety Population

Reporting Groups

	Description
NVA237 50µg	NVA237 50 µg capsules were supplied by Novartis for inhalation once daily with Concept 1 device.
Placebo	Matching placebo capsules were supplied by Novartis for inhalation once daily with Concept 1 device.

Measured Values

	NVA237 50µg	Placebo
Number of Participants Analyzed [units: participants]	**31**	**33**
Number of Participants Who Experienced Adverse Events (AEs), Serious Adverse Events (SAEs) [units: Participants]		
Overall Adverse Events	**2**	**4**
Serious Adverse Events (SAEs)	**0**	**0**

No statistical analysis provided for Number of Participants Who Experienced Adverse Events (AEs), Serious Adverse Events (SAEs)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Placebo	Matching placebo capsules were supplied by Novartis for inhalation once daily with Concept 1 device.
NVA237 50 µg	NVA237 50 µg capsules were supplied by Novartis for inhalation once daily with Concept 1 device.

Serious Adverse Events

	Placebo	NVA237 50 µg
Total, serious adverse events		
# participants affected / at risk	**0/33 (0.00%)**	**0/31 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Matching placebo capsules were supplied by Novartis for inhalation once daily with Concept 1 device.
NVA237 50 µg	NVA237 50 µg capsules were supplied by Novartis for inhalation once daily with Concept 1 device.

Other Adverse Events

	Placebo	NVA237 50 µg
Total, other (not including serious) adverse events		
# participants affected / at risk	**2/33 (6.06%)**	**0/31 (0.00%)**
Gastrointestinal disorders		
Gastrointestinal disorders		
# participants affected / at risk	**2/33 (6.06%)**	**0/31 (0.00%)**
# events	**2**	**0**

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

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00856193 History of Changes
Other Study ID Numbers:	**CNVA237A2207** 2008-006849-28 (EudraCT Number)
Study First Received:	March 4, 2009
Results First Received:	January 20, 2011
Last Updated:	June 8, 2011
Health Authority:	United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medical Devices

Russia: Ministry of Health of the Russian Federation