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Trial record **1 of 1** for: CNVA237A2205

Previous Study | Return to List | Next Study

Efficacy and Safety of Four Doses of Glycopyrronium Bromide (NVA237) in Patients With Stable Chronic Obstructive Pulmonary Disease (COPD), in Comparison to an Active Comparator Tiotropium

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00501852

First received: July 13, 2007
Last updated: May 3, 2012
Last verified: December 2010
History of Changes

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

Results First Received: December 22, 2010

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

	Drug: Tiotropium

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
Overall Study	No text entered.

Participant Flow: Overall Study

	Overall Study
STARTED	**83**
NVA237 12.5µg	**55**
NVA237 25µg	**51**
NVA237 50µg	**53**
NVA237 100µg	**54**
Placebo	**55**
Tiotropium	

	55
COMPLETED	78
NOT COMPLETED	5
Adverse Event	3
Withdrawal by Subject	2

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Overall Study	No text entered.

Baseline Measures

	Overall Study
Number of Participants [units: participants]	83
Age [units: years] Mean (Standard Deviation)	64.4 (9.05)
Age, Customized	

[units: participants]	
40-64 years	**39**
>= 65 years	**44**
Gender [units: participants]	
Female	**14**
Male	**69**
Race (NIH/OMB) [units: participants]	
American Indian or Alaska Native	**0**
Asian	**25**
Native Hawaiian or Other Pacific Islander	**0**
Black or African American	**0**
White	**58**
More than one race	**0**
Unknown or Not Reported	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in 1 Second (FEV1) Following 7 Days of Treatment [Time Frame: Day 7]

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) Following 7 Days of Treatment

Measure Description	FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation, measured through spirometry testing. The trough in FEV1 was defined as the mean of two measurements at 23h 15min and 23h 45min post dosing.
Time Frame	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.
Modified Intent-to-Treat (mITT) population. The modified intent-to-treat (mITT) population included all randomized patients who received at least one dose of study drug. Patients were analyzed according to the treatment they received.

Reporting Groups

	Description
NVA237 12.5 ug	12.5 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 25 ug	25 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 50 ug	50 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 100 ug	100 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
Placebo	Placebo via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
Tiotropium Bromide	18 µg od via Handihaler inhaler. Tiotropium was given open-label. At baseline visits for each of the 4 double-blind

	treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.

Measured Values

	NVA237 12.5 ug	NVA237 25 ug	NVA237 50 ug	NVA237 100 ug	Placebo	Tiotropium Bromide
Number of Participants Analyzed [units: participants]	**55**	**51**	**53**	**53**	**49**	**55**
Trough Forced Expiratory Volume in 1 Second (FEV1) Following 7 Days of Treatment [units: Liters] Least Squares Mean (Standard Error)	**1.317 (0.0145)**	**1.333 (0.0151)**	**1.374 (0.0148)**	**1.385 (0.0148)**	**1.243 (0.0156)**	**1.370 (0.0145)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) Following 7 Days of Treatment

2. Secondary: Least Squares Means of FEV1 (L) at Day 1, by Timepoint [Time Frame: Day 1]

Measure Type	Secondary
Measure Title	Least Squares Means of FEV1 (L) at Day 1, by Timepoint
Measure Description	FEV1 was measured at 5, 15, 30 minutes, 1, 2, 3, 4, 5, 23 hours and 15 minutes, and 23 hours and 45 minutes post dose.
Time Frame	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.
No text entered.

Reporting Groups

	Description
NVA237 12.5 ug	12.5 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 25 ug	25 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 50 ug	50 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 100 ug	100 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
Placebo	Placebo via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
Tiotropium Bromide	18 µg od via Handihaler inhaler. Tiotropium was given open-label. At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.

Measured Values

	NVA237 12.5 ug	NVA237 25 ug	NVA237 50 ug	NVA237 100 ug	Placebo	Tiotropium Bromide
Number of Participants Analyzed [units: participants]	**55**	**51**	**53**	**54**	**55**	**55**
Least Squares Means of FEV1 (L) at Day 1, by Timepoint [units: Liters] Least Squares Mean (Standard Error)						

Day 1: -45 minutes	**1.25 (0.00)**	**1.24 (0.00)**	**1.24 (0.00)**	**1.24 (0.00)**	**1.24 (0.00)**	**1.25 (0.00)**
Day 1: -15 minutes	**1.25 (0.00)**	**1.26 (0.00)**	**1.25 (0.00)**	**1.26 (0.00)**	**1.26 (0.00)**	**1.25 (0.00)**
Day 1: 5 minutes	**1.30 (0.01)**	**1.34 (0.01)**	**1.34 (0.01)**	**1.35 (0.01)**	**1.26 (0.01)**	**1.31 (0.01)**
Day 1: 15 minutes	**1.36 (0.01)**	**1.41 (0.01)**	**1.41 (0.01)**	**1.41 (0.01)**	**1.27 (0.01)**	**1.35 (0.01)**
Day 1: 30 minutes	**1.41 (0.01)**	**1.44 (0.01)**	**1.44 (0.01)**	**1.45 (0.01)**	**1.28 (0.01)**	**1.40 (0.01)**
Day 1: 1 hour	**1.42 (0.01)**	**1.46 (0.01)**	**1.46 (0.01)**	**1.48 (0.01)**	**1.28 (0.01)**	**1.41 (0.01)**
Day 1: 2 hours	**1.44 (0.01)**	**1.48 (0.01)**	**1.50 (0.01)**	**1.52 (0.01)**	**1.31 (0.01)**	**1.45 (0.01)**
Day 1: 3 hours	**1.43 (0.01)**	**1.48 (0.01)**	**1.49 (0.01)**	**1.53 (0.01)**	**1.30 (0.01)**	**1.46 (0.01)**
Day 1: 4 hours	**1.41 (0.01)**	**1.45 (0.01)**	**1.49 (0.01)**	**1.52 (0.01)**	**1.30 (0.01)**	**1.46 (0.01)**
Day 1: 5 hours	**1.39 (0.01)**	**1.43 (0.01)**	**1.44 (0.01)**	**1.49 (0.01)**	**1.28 (0.01)**	**1.45 (0.01)**
Day 1: 23 hours 15 minutes	**1.27 (0.01)**	**1.29 (0.01)**	**1.36 (0.01)**	**1.37 (0.01)**	**1.24 (0.01)**	**1.35 (0.01)**
Day 1: 23 hours 45 minutes	**1.29 (0.01)**	**1.31 (0.01)**	**1.37 (0.01)**	**1.39 (0.01)**	**1.25 (0.01)**	**1.37 (0.01)**
Trough	**1.28 (0.01)**	**1.30 (0.01)**	**1.36 (0.01)**	**1.38 (0.01)**	**1.24 (0.01)**	**1.36 (0.01)**

No statistical analysis provided for Least Squares Means of FEV1 (L) at Day 1, by Timepoint

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
NVA237 12.5 ug	12.5 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 25 ug	25 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 50 ug	50 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 100 ug	100 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
Placebo	Placebo via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
Tiotropium Bromide	18 µg od via Handihaler inhaler. Tiotropium was given open-label. At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.

Serious Adverse Events

	NVA237 12.5 ug	NVA237 25 ug	NVA237 50 ug	NVA237 100 ug	Placebo	Tiotropium Bromide
Total, serious adverse events						
# participants affected / at risk	**0/55 (0.00%)**	**0/51 (0.00%)**	**1/53 (1.89%)**	**0/54 (0.00%)**	**0/55 (0.00%)**	**0/54 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Gastric cancer † 1						
# participants affected / at risk	**0/55 (0.00%)**	**0/51 (0.00%)**	**1/53 (1.89%)**	**0/54 (0.00%)**	**0/55 (0.00%)**	**0/54 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
NVA237 12.5 ug	12.5 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between

	each sequence.
NVA237 25 ug	25 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 50 ug	50 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
NVA237 100 ug	100 µg daily via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
Placebo	Placebo via single-dose dry-powder inhaler (SDDPI). At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.
Tiotropium Bromide	18 µg od via Handihaler inhaler. Tiotropium was given open-label. At baseline visits for each of the 4 double-blind treatment periods, patients were randomized to one of 30 treatment sequences. There was a 7 day washout period between each sequence.

Other Adverse Events

	NVA237 12.5 ug	NVA237 25 ug	NVA237 50 ug	NVA237 100 ug	Placebo	Tiotropium Bromide
Total, other (not including serious) adverse events						
# participants affected / at risk	**6/55 (10.91%)**	**4/51 (7.84%)**	**1/53 (1.89%)**	**2/54 (3.70%)**	**3/55 (5.45%)**	**2/54 (3.70%)**
Infections and infestations						
Rhinitis † [1]						
# participants affected / at risk	**0/55 (0.00%)**	**3/51 (5.88%)**	**0/53 (0.00%)**	**0/54 (0.00%)**	**1/55 (1.82%)**	**0/54 (0.00%)**
Nervous system disorders						

Headache † 1						
# participants affected / at risk	**4/55 (7.27%)**	**1/51 (1.96%)**	**1/53 (1.89%)**	**1/54 (1.85%)**	**0/55 (0.00%)**	**2/54 (3.70%)**
Respiratory, thoracic and mediastinal disorders						
Cough † 1						
# participants affected / at risk	**3/55 (5.45%)**	**0/51 (0.00%)**	**0/53 (0.00%)**	**1/54 (1.85%)**	**2/55 (3.64%)**	**0/54 (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 (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:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00501852 History of Changes
Other Study ID Numbers:	**CNVA237A2205**
Study First Received:	July 13, 2007
Results First Received:	December 22, 2010
Last Updated:	May 3, 2012
Health Authority:	Japan: Ministry of Health, Labor and Welfare Belgium: Federal Agency for Medicinal Products and Health Products France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)