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Trial record **1 of 1** for: CNVA237A2208

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Efficacy and Safety of NVA237 in Patients With Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01119950

First received: May 5, 2010
Last updated: March 3, 2015
Last verified: March 2015
History of Changes

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Results First Received: January 23, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: NVA237 12.5 µg once daily Drug: NVA237 25.0 µg once daily Drug: NVA237 12.5 µg twice daily Drug: NVA237 50.0 µg once daily Drug: NVA237 25.0 µg twice daily Drug: NVA237 100.0 µg once daily

	Drug: NVA237 50.0 µg twice daily Drug: Placebo to NVA237 once daily

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
Participants were randomized to 1 of 8 treatment groups during period 1; participants were then switched to a different treatment group during period 2 after a 7 days wash out. Each period lasted up to 29 days.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
For this crossover study, a participant is counted in 2 treatment groups

Reporting Groups

	Description
Overall Study	For the overall study, 388 participants were randomized and 1 non-randomized participant received drug in error and was discontinued. This participant was excluded from randomized number of patients but included in number of treated participants and in the safety set. Out of the 388 participants randomized, 341 completed study treatment and 47 discontinued, including 3 misrandomized participants who did not receive any study medication.

Participant Flow: Overall Study

	Overall Study
STARTED	**388** [1]
NVA237 12.5 ug q.d.	**96** [2]
NVA237 25 ug q.d.	**99** [3]
NVA237 12.5 ug b.i.d.	**99** [4]
NVA237 50 ug q.d.	**96** [5]

NVA237 25 ug b.i.d.	**100** [6]
NVA237 100 ug q.d.	**98** [7]
NVA237 50 ug b.i.d.	**94** [8]
Placebo	**94** [9]
COMPLETED	**341** [10]
NOT COMPLETED	**47**
Adverse Event	**25**
Withdrawal by Subject	**9**
Protocol Violation	**5**
Lost to Follow-up	**4**
Administrative	**2**
Abnormal lab value	**1**
Death	**1**

[1] These participants were randomized to 2 different treatment sequences during period 1 and 2.
[2] 5 randomized and 2 misrandomized patients did not receive study drug, 80 completed, 9 discontinued.
[3] 3 randomized participants did not receive study drug, 91 completed treatment, 5 discontinued.
[4] 4 randomized participants did not receive study drug, 93 completed treatment, 2 discontinued.
[5] 4 randomized participants did not receive study drug, 89 completed treatment, 3 discontinued.
[6] 4 randomized participants did not receive study drug, 89 completed treatment, 7 discontinued.
[7] 2 randomized participants did not receive study drug, 92 completed treatment, 4 discontinued.
[8] 6 randomized and 1 misrandomized patients did not receive study drug, 82 completed, 5 discontinued.
[9] 3 randomized participants did not receive study drug, 82 completed treatment, 5 discontinued.
[10] These participants completed both periods 1 and 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.
Baseline/demographic measures are based on safety set

Reporting Groups

	Description
All Participants	All participants in the safety set

Baseline Measures

	All Participants
Number of Participants [units: participants]	**386**
Age [units: Years] Mean (Standard Deviation)	**61.2 (7.91)**
Gender [units: Participants]	
Female	**251**
Male	**135**

Outcome Measures

Hide All Outcome Measures

1. Primary: Maximal Response of Incremental Once Daily and Twice Daily Doses of NVA237 That Each Dose Achieves in Relation to the Maximal Effect of NVA237 on Trough Forced Expiratory Volume in One Second at Day 28 [Time Frame: Day 28]

Measure Type	Primary
Measure Title	Maximal Response of Incremental Once Daily and Twice Daily Doses of NVA237 That Each Dose Achieves in Relation to the Maximal Effect of NVA237 on Trough Forced Expiratory Volume in One Second at Day 28

Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. The maximal response of incremental once daily and twice daily doses of NVA237 that each dose achieves in relation to the maximal effect of NVA237 on Trough FEV1 was measured at Day 28. FEV1 was measured in response to all doses administered (see Outcome Measure #19). All trough FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All trough FEV1 data are reported as a percentage of the theoretical maximal response. Trough FEV1 was defined as the mean of the 23 hour 15 minute and 23 hour 45 minute post-dose values.
Time Frame	Day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

			NVA237		**NVA237**	**NVA237**	**NVA237**

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	12.5 µg b.i.d.	NVA237 50.0 µg q.d.	25.0 µg b.i.d.	100.0 µg q.d.	50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**81**	**88**	**90**	**88**	**87**	**90**	**81**
Maximal Response of Incremental Once Daily and Twice Daily Doses of NVA237 That Each Dose Achieves in Relation to the Maximal Effect of NVA237 on Trough Forced Expiratory Volume in One Second at Day 28 [units: Percentage of maximal response] Mean (90% Confidence Interval)	**27.1 (16.4 to 44.3)**	**42.0 (26.5 to 61.4)**	**61.6 (36.6 to 82.1)**	**58.5 (37.5 to 76.2)**	**75.5 (48.7 to 90.2)**	**73.0 (49.0 to 86.5)**	**85.4 (60.4 to 94.8)**

No statistical analysis provided for Maximal Response of Incremental Once Daily and Twice Daily Doses of NVA237 That Each Dose Achieves in Relation to the Maximal Effect of NVA237 on Trough Forced Expiratory Volume in One Second at Day 28

2. Secondary: Trough Forced Expiratory Volume in One Second for Once and Twice Daily Regimens of NVA237 for the Same Total Daily Dose of NVA237 [Time Frame: day 28]

Measure Type	Secondary
Measure Title	Trough Forced Expiratory Volume in One Second for Once and Twice Daily Regimens of NVA237 for the Same Total Daily Dose of NVA237
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. FEV1 was measured between dosing regimens (over the range 20 micrograms to 55 micrograms total daily dose) after 28 days of treatment. Mean trough FEV1 was measured in response to all doses administered (12.5 µg q.d., 25.0 µg q.d., 12.5 µg b.i.d., 50 µg q.d., 25 µg b.i.d., 100 µg q.d., 50.0 µg b.i.d., and Placebo; see Outcome Measure # 19), and was used to compute modeled dose-response curves for once-daily and twice-daily regimens separately. The difference between those curves was computed at pre-specified theoretical doses (20 µg, 25 µg, 30 µg, 35 µg, 40 µg, 45 µg, 50 µg, and 55 µg) chosen at points likely to show the largest differences between the once-daily and twice-daily regimens. The theoretical responses to each dosing schedule separately and the difference between the once-daily and twice-daily regimens are represented below.

Time Frame	day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
Overall Study	A statistical modeling process was used to achieve the key objective. A set of 4 candidate models based on the Emax dose-response shape was derived plus their sigmoidal Emax counterparts (a total of 8 models) that describe the evolution of dose response over time. A model-averaging process was then employed to obtain response predictions as the weighted average of individual model predictions and confidence limits derived using a simulation-based procedure.

Measured Values

	Overall Study
Number of Participants Analyzed **[units: participants]**	**385**
Trough Forced Expiratory Volume in One Second for Once and Twice Daily Regimens of NVA237 for the Same Total Daily Dose of NVA237 **[units: Liters]** **Mean (90% Confidence Interval)**	
Total daily dose 20 ug	**0.037 (0.013 to 0.053)**
Total daily dose 25 ug	**0.037 (0.013 to 0.052)**
Total daily dose 30 ug	**0.036 (0.013 to 0.051)**

Total daily dose 35 ug	**0.035 (0.013 to 0.050)**
Total daily dose 40 ug	**0.034 (0.013 to 0.049)**
Total daily dose 45 ug	**0.033 (0.013 to 0.047)**
Total daily dose 50 ug	**0.032 (0.012 to 0.046)**
Total daily dose 55 ug	**0.031 (0.012 to 0.045)**

No statistical analysis provided for Trough Forced Expiratory Volume in One Second for Once and Twice Daily Regimens of NVA237 for the Same Total Daily Dose of NVA237

3. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours at Day 28 of Treatment [Time Frame: 5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours at Day 28 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on FEV1 Area Under the Curve (AUC) 0-24 hours at day 28 of treatment was calculated from measurements taken at 5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28. AUC FEV1 was measured in response to all doses administered (see Outcome Measure #20). All FEV1 responses to active

	doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**82**	**90**	**91**	**90**	**92**	**91**	**82**
Percentage of the Maximal Response of							

NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours at Day 28 of Treatment [units: Percentage of maximal response * hours] Mean (90% Confidence Interval)	**28.9 (18.7 to 41.6)**	**44.8 (31.6 to 58.8)**	**49.0 (34.1 to 64.1)**	**61.9 (48.0 to 74.0)**	**65.7 (50.9 to 78.1)**	**76.4 (64.8 to 85.1)**	**79.3 (67.5 to 87.7)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours at Day 28 of Treatment

4. Secondary: Forced Expiratory Volume in One Second AUC 0-24 Hours for Once and Twice Daily Regimens of NVA237 for the Same Total Daily Dose of NVA237, After 28 Days of Treatment [Time Frame: -25 min,-15 min (predose); 5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in One Second AUC 0-24 Hours for Once and Twice Daily Regimens of NVA237 for the Same Total Daily Dose of NVA237, After 28 Days of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. The Area Under the Curve (AUC) 0-24 hours FEV1 between dosing regimens over the range 20 micrograms to 55 micrograms total daily dose at -25 min,-15 min (predose); 5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28. AUC 0-24 hours FEV1 was measured in response to all doses administered (12.5 µg q.d., 25.0 µg q.d., 12.5 µg b.i.d., 50 µg q.d., 25 µg b.i.d., 100 µg q.d., 50.0 µg b.i.d., and Placebo; see Outcome Measure # 20), and was used to compute modeled dose-response curves for once-daily and twice-daily regimens separately. The difference between those curves was computed at pre-specified theoretical doses (20 µg, 25 µg, 30 µg, 35 µg, 40 µg, 45 µg, 50 µg, and 55 µg) chosen at points likely to show the largest differences between the once-daily and twice-daily regimens.
Time Frame	-25 min,-15 min (predose); 5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28
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.

Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
Overall Study	A statistical modeling process was used to achieve the key objective. A set of 4 candidate models based on the Emax dose-response shape was derived plus their sigmoidal Emax counterparts (a total of 8 models) that describe the evolution of dose response over time. A model-averaging process was then employed to obtain response predictions as the weighted average of individual model predictions and confidence limits derived using a simulation-based procedure.

Measured Values

	Overall Study
Number of Participants Analyzed **[units: participants]**	**385**
Forced Expiratory Volume in One Second AUC 0-24 Hours for Once and Twice Daily Regimens of NVA237 for the Same Total Daily Dose of NVA237, After 28 Days of Treatment **[units: Liters]** **Mean (90% Confidence Interval)**	
Total daily dose 20 ug	**0.008** **(-0.008 to 0.023)**
Total daily dose 25 ug	**0.008** **(-0.008 to 0.024)**
Total daily dose 30 ug	**0.008** **(-0.008 to 0.024)**
Total daily dose 35 ug	**0.008** **(-0.008 to 0.023)**

Total daily dose 40 ug	**0.008 (-0.008 to 0.023)**
Total daily dose 45 ug	**0.008 (-0.008 to 0.022)**
Total daily dose 50 ug	**0.008 (-0.008 to 0.022)**
Total daily dose 55 ug	**0.007 (-0.007 to 0.021)**

No statistical analysis provided for Forced Expiratory Volume in One Second AUC 0-24 Hours for Once and Twice Daily Regimens of NVA237 for the Same Total Daily Dose of NVA237, After 28 Days of Treatment

5. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve at Different Time Points (0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours) on Day 28 [Time Frame: 5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve at Different Time Points (0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours) on Day 28
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on FEV1 Area Under the Curve (AUC) 0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours were calculated from measurements taken at: 5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28.

	AUC FEV1 was measured in response to all doses administered (see Outcome Measure #21). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	**NVA237 25.0 µg q.d.**	**NVA237 12.5 µg b.i.d.**	**NVA237 50.0 µg q.d.**	**NVA237 25.0 µg b.i.d.**	**NVA237 100.0 µg q.d.**	**NVA237 50.0 µg b.i.d.**
Number of Participants Analyzed [units: participants]	**82**	**90**	**91**	**90**	**92**	**91**	**82**

Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve at Different Time Points (0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours) on Day 28 **[units: Percentage of maximal response* hours]** **Mean (90% Confidence Interval)**							
AUC 0-4h (n=82,90,91,89,92,91,82)	**50.8** **(38.7 to 63.6)**	**66.9** **(53.7 to 77.7)**	**58.9** **(45.9 to 71.5)**	**79.7** **(67.4 to 87.4)**	**73.7** **(60.6 to 83.4)**	**88.3** **(77.8 to 93.3)**	**84.4** **(73.0 to 91.0)**
AUC 0-8h (n=82,90,91,90,92,91,82)	**45.8** **(33.2 to 58.8)**	**62.8** **(49.9 to 74.1)**	**55.5** **(42.0 to 68.4)**	**77.1** **(66.6 to 85.1)**	**71.4** **(59.1 to 81.2)**	**87.1** **(79.9 to 91.9)**	**83.3** **(74.3 to 89.7)**
AUC 0-12h (n=82,90,91,90,92,91,82)	**41.1** **(28.8 to 54.5)**	**58.3** **(44.7 to 70.6)**	**50.5** **(37.0 to 64.1)**	**73.6** **(61.8 to 82.8)**	**67.1** **(54.0 to 78.1)**	**84.8** **(76.4 to 90.6)**	**80.3** **(70.1 to 87.7)**
AUC 12-24h (n=82,90,91,89,92,91,81)	**25.6** **(15.5 to 42.5)**	**40.1** **(24.2 to 59.6)**	**56.6** **(31.4 to 78.2)**	**56.4** **(33.0 to 74.7)**	**71.4** **(41.5 to 87.8)**	**71.2** **(42.6 to 85.5)**	**82.4** **(51.2 to 93.5)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve at Different Time Points (0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours) on Day 28

6. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second at 12 Hours at Day 28 of Treatment [Time Frame: 12 hours on day 28]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second at 12 Hours at Day 28 of Treatment

Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response within different doses/regimens of NVA237 was measured using FEV1 at 12 hours on day 28 of treatment. FEV1 was measured in response to all doses administered (see Outcome Measure #22). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	12 hours on day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.

Number of Participants Analyzed [units: participants]	**79**	**88**	**91**	**85**	**87**	**88**	**78**
Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second at 12 Hours at Day 28 of Treatment [units: Percentage of maximal response] Mean (90% Confidence Interval)	**27.1 (14.7 to 44.6)**	**42.7 (25.7 to 61.7)**	**35.5 (20.4 to 54.0)**	**59.8 (40.9 to 76.3)**	**52.4 (33.9 to 70.2)**	**74.9 (58.0 to 86.6)**	**68.7 (50.7 to 82.5)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second at 12 Hours at Day 28 of Treatment

7. Secondary: Percentage of the Maximal Response of NVA237 Doses on Peak Forced Expiratory Volume in One Second at Day 28 of Treatment [Time Frame: day 28]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Peak Forced Expiratory Volume in One Second at Day 28 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Peak FEV1 is the maximum FEV1 recorded in a pre-determined period of time. Percentage of the maximal response of NVA237 within different doses/regimens of NVA237 on Peak FEV1 was measured at day 28 of treatment. Peak FEV1 was measured in response to all doses administered (see Outcome Measure #23). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	day 28
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.

Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**82**	**90**	**91**	**89**	**92**	**91**	**82**
Percentage of the Maximal Response of NVA237 Doses on Peak Forced Expiratory Volume in One Second at Day 28 of Treatment [units: Percentage of maximal response] Mean (90% Confidence Interval)	**53.3 (41.2 to 65.5)**	**69.2 (56.7 to 79.2)**	**61.1 (48.2 to 73.4)**	**81.5 (71.1 to 88.4)**	**75.6 (63.4 to 84.7)**	**89.6 (82.4 to 93.9)**	**85.8 (76.5 to 91.7)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Peak Forced Expiratory Volume in One Second at Day 28 of Treatment

8. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Vital Capacity at Day 28 of Treatment [Time Frame: day 28]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Vital Capacity at Day 28 of Treatment
Measure Description	Percentage of the maximal response of NVA237 within different doses/regimens of NVA237 on Forced Vital Capacity (FVC) was measured at day 28 of treatment. FVC is the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. FVC at day 28 of treatment was measured via spirometry (see Outcome Measure #24). All FVC responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FVC data are reported as a percentage of the theoretical maximal response.
Time Frame	day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	81	88	90	88	87	90	81
Percentage of the Maximal Response of NVA237 Doses on Forced Vital Capacity at Day 28 of Treatment [units: Percentage of maximal response] Mean (90% Confidence Interval)	23.3 (11.3 to 45.3)	37.4 (19.8 to 62.7)	53.6 (26.5 to 81.2)	54.0 (30.9 to 77.2)	69.3 (38.6 to 89.7)	69.7 (43.6 to 87.2)	81.4 (52.5 to 94.6)

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Vital Capacity at Day 28 of Treatment

9. Secondary: Percentage of the Maximal Response of NVA237 Doses on Trough Forced Expiratory Volume in One Second at Days 1, 7 and 14 [Time Frame: Days 1, 7 and 14]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Trough Forced Expiratory Volume in One Second at Days 1, 7 and 14
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on Trough FEV1 was measured on Days 1, 7 and 14. Through FEV1 was measured in response to all doses administered (see Outcome Measure #25). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response. Trough FEV1 was defined as the mean of the 23 hour 15 minute and 23 hour 45 minute post-dose values.
Time Frame	Days 1, 7 and 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.

Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**88**	**92**	**91**	**91**	**95**	**94**	**87**
Percentage of the Maximal Response of NVA237 Doses on Trough Forced Expiratory Volume in One Second at Days 1, 7 and 14 [units: Percentage of maximal response] Mean (90% Confidence Interval)							
Day 1 (n= 88,92,91, 90, 94, 94, 87)	**28.5 (17.5 to 45.3)**	**43.8 (27.8 to 62.3)**	**63.3 (37.9 to 82.5)**	**60.1 (38.2 to 76.8)**	**76.7 (49.3 to 90.5)**	**74.3 (48.6 to 86.9)**	**86.2 (59.8 to 95.0)**

Day 7 (n= 87,92,90, 91, 95, 93, 85)	**27.1 (16.3 to 44.3)**	**42.0 (26.3 to 61.4)**	**61.6 (36.4 to 82.1)**	**58.5 (37.3 to 76.1)**	**75.5 (48.3 to 90.1)**	**73.0 (48.7 to 86.4)**	**85.4 (59.8 to 94.8)**
Day 14 (n= 85,90,91, 88, 94, 93, 81)	**27.1 (16.4 to 44.3)**	**42.0 (26.4 to 61.4)**	**61.6 (36.6 to 82.1)**	**58.5 (37.4 to 76.1)**	**75.5 (48.5 to 90.2)**	**73.0 (48.8 to 86.5)**	**85.4 (60.1 to 94.8)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Trough Forced Expiratory Volume in One Second at Days 1, 7 and 14

10. Secondary: Percentage of the Maximal Effect of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours on Days 1 and 14 of Treatment [Time Frame: 5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on days 1 and 14]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Effect of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours on Days 1 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on FEV1 Area Under the Curve (AUC) 0-24 hours, was calculated from measurements taken at 5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on days 1 and 14. FEV1 AUC 0-24 hours was measured on days 1 and 14 of treatment in response to all doses administered (see Outcome Measure #26). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on days 1 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	**NVA237 25.0 µg q.d.**	**NVA237 12.5 µg b.i.d.**	**NVA237 50.0 µg q.d.**	**NVA237 25.0 µg b.i.d.**	**NVA237 100.0 µg q.d.**	**NVA237 50.0 µg b.i.d.**
Number of Participants Analyzed **[units: participants]**	**89**	**94**	**93**	**92**	**96**	**96**	**87**
Percentage of the Maximal Effect of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours on Days 1 and 14 of Treatment **[units: Percentage of maximal response* hours]** **Mean (90% Confidence Interval)**							

Day 1 (n= 89,94,93,92,96,96,87)	**38.3 (25.3 to 53.4)**	**55.4 (40.4 to 69.6)**	**59.5 (42.8 to 74.2)**	**71.3 (57.5 to 82.1)**	**74.6 (60.0 to 85.2)**	**83.2 (73.0 to 90.2)**	**85.4 (75.0 to 92.0)**
Day 14 (n= 86,92,91,91,95,93,84)	**28.9 (18.7 to 41.6)**	**44.8 (31.6 to 58.8)**	**49.0 (34.1 to 64.1)**	**61.9 (48.0 to 74.0)**	**65.7 (50.9 to 78.1)**	**76.4 (64.8 to 85.1)**	**79.3 (67.5 to 87.7)**

No statistical analysis provided for Percentage of the Maximal Effect of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours on Days 1 and 14 of Treatment

11. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-4 Hours on Days 1, 7 and 14 of Treatment [Time Frame: 5 min,15 min, 1,2,3,4 hours (postdose) on Days 1, 7 and 14]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-4 Hours on Days 1, 7 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on FEV1 Area Under the Curve (AUC) 0-4 hours was calculated from measurements taken at 5 min,15 min, 1,2,3,4 hours (postdose) on Days 1, 7 and 14, in response to all doses administered (see Outcome Measure #27). All AUC FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	5 min,15 min, 1,2,3,4 hours (postdose) on Days 1, 7 and 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.

Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**92**	**96**	**96**	**86**
Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-4 Hours on Days 1, 7 and 14 of Treatment [units: Percentage of maximal response* hours] Mean (90% Confidence Interval)							
Day 1 (n=89,94,93,91,96,96,86)	**58.4 (44.4 to 71.8)**	**73.2 (59.1 to 83.6)**	**66.1 (51.6 to 78.6)**	**84.1 (72.0 to 91.1)**	**79.1 (65.6 to 88.0)**	**91.1 (81.5 to 95.3)**	**88.0 (77.1 to 93.6)**

Day 7 (n=87,93,90,92,95,94,85)	**50.8 (38.7 to 63.6)**	**66.9 (53.7 to 77.7)**	**58.9 (45.9 to 71.5)**	**79.7 (67.4 to 87.4)**	**73.7 (60.6 to 83.4)**	**88.3 (77.8 to 93.3)**	**84.4 (73.0 to 91.0)**
Day 14 (n=86,92,91,91,95,93,84)	**50.8 (38.7 to 63.6)**	**66.9 (53.7 to 77.7)**	**58.9 (45.9 to 71.5)**	**79.7 (67.4 to 87.4)**	**73.7 (60.6 to 83.4)**	**88.3 (77.8 to 93.3)**	**84.4 (73.0 to 91.0)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-4 Hours on Days 1, 7 and 14 of Treatment

12. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second of Area Under the Curve 0-8 Hours Days 1, 7, and 14 [Time Frame: at 5 min,15 min, 1,2,3,4,6,8 hours (postdose) on days 1, 7 and 14]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second of Area Under the Curve 0-8 Hours Days 1, 7, and 14
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on FEV1 Area Under the Curve (AUC) 0-8 was calculated from measurements taken at 5 min,15 min, 1,2,3,4,6,8 hours (postdose) on days 1, 7, and 14. AUC FEV1 was measured in response to all doses administered (see Outcome Measure #28). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	at 5 min,15 min, 1,2,3,4,6,8 hours (postdose) on days 1, 7 and 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.

Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**92**	**96**	**96**	**87**
Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second of Area Under the Curve 0-8 Hours Days 1, 7, and 14 [units: Percentage of maximal response* hours] Mean (90% Confidence Interval)							
Day 1 (n=89, 94, 93, 91, 96, 96, 87)	**54.2 (40.1 to 67.8)**	**70.3 (57.2 to 80.8)**	**63.6 (49.0 to 76.3)**	**82.6 (72.8 to 89.4)**	**77.8 (65.8 to 86.5)**	**90.5 (84.3 to 94.4)**	**87.5 (79.4 to 92.8)**
	45.8	**62.8**	**55.5**	**77.1**	**71.4**	**87.1**	**83.3**

Day 7 (n= 87, 93, 91, 92, 95, 94, 85)	**(33.2 to 58.8)**	**(49.9 to 74.1)**	**(42.0 to 68.4)**	**(66.6 to 85.1)**	**(59.1 to 81.2)**	**(79.9 to 91.9)**	**(74.3 to 89.7)**
Day 14 (n=86, 92, 91, 91, 95, 93, 84)	**45.8 (33.2 to 58.8)**	**62.8 (49.9 to 74.1)**	**55.5 (42.0 to 68.4)**	**77.1 (66.6 to 85.1)**	**71.4 (59.1 to 81.2)**	**87.1 (79.9 to 91.9)**	**83.3 (74.3 to 89.7)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second of Area Under the Curve 0-8 Hours Days 1, 7, and 14

13. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-12 Hours at Day 1 and 14 of Treatment [Time Frame: 5 min,15 min, 1,2,3,4,6,8,10 hours, 11h 55 min (postdose) on days 1 and 14]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-12 Hours at Day 1 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses was calculated on FEV1 Area Under the Curve (AUC) 0-12 hours from measurements taken at at 5 min,15 min, 1,2,3,4,6,8,10 hours, 11h 55 min (postdose) on days 1 and 14 in response to all doses administered (see Outcome Measure #29). All AUC FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	5 min,15 min, 1,2,3,4,6,8,10 hours, 11h 55 min (postdose) on days 1 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**91**	**96**	**96**	**87**
Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-12 Hours at Day 1 and 14 of Treatment [units: Percentage of maximal response* hours] Mean (90% Confidence Interval)							
Day 1 (n=89, 94, 93, 91, 96, 96, 87)	**49.5 (35.5 to 63.6)**	**66.2 (52.4 to 77.8)**	**58.8 (44.0 to 72.3)**	**79.6 (68.7 to 87.5)**	**74.1 (61.1 to 83.9)**	**88.7 (81.5 to 93.3)**	**85.1 (75.9 to 91.3)**
Day 14 (n=86, 92, 91, 91, 95, 93, 84)	**41.1 (28.8 to 54.5)**	**58.3 (44.7 to 70.6)**	**50.5 (37.0 to 64.1)**	**73.6 (61.8 to 82.8)**	**67.1 (54.0 to 78.1)**	**84.8 (76.4 to 90.6)**	**80.3 (70.1 to 87.7)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second Area Under the Curve 0-12 Hours at Day 1 and 14 of Treatment

14. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second of Area Under the Curve 12-24 Hours Over Days 1, and 14 of Treatment [Time Frame: 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on Days 1 and 14]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second of Area Under the Curve 12-24 Hours Over Days 1, and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 on FEV1 Area under the curve (AUC) 12-24 hours was calculated from measurements taken at 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on Days 1 and 14. AUC FEV1 was measured in response to all doses administered (see Outcome Measure #30). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on Days 1 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily

NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**92**	**96**	**96**	**87**
Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second of Area Under the Curve 12-24 Hours Over Days 1, and 14 of Treatment [units: Percentage of maximal response* hours] Mean (90% Confidence Interval)							
Day 1 (n=89, 94, 93, 92, 96, 96, 87)	**23.9 (1.2 to 90.7)**	**37.9 (2.4 to 95.2)**	**54.4 (4.5 to 97.8)**	**54.1 (4.7 to 97.6)**	**69.5 (8.6 to 98.9)**	**69.3 (9.0 to 98.8)**	**81.1 (15.5 to 99.5)**
Day 14 (n= 86, 92, 91, 91, 95, 93, 84)	**25.6 (15.5 to 42.5)**	**40.1 (24.2 to 59.6)**	**56.6 (31.3 to 78.2)**	**56.4 (32.9 to 74.7)**	**71.4 (41.4 to 87.8)**	**71.2 (42.5 to 85.5)**	**82.4 (51.2 to 93.5)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second of Area Under the Curve 12-24 Hours Over Days 1, and 14 of Treatment

15. Secondary: Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second at 12 Hours on Days 1 and 14 of Treatment [Time Frame: Days 1 and 14]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second at 12 Hours on Days 1 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on FEV1 at 12 hours was measured on days 1 and 14. FEV1 was measured in response to all doses administered (see Outcome Measure #31). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	Days 1 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily

NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**84**	**91**	**91**	**90**	**90**	**92**	**83**
Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second at 12 Hours on Days 1 and 14 of Treatment [units: Percentage of maximal response] Mean (90% Confidence Interval)							
Day 1 (n=83, 90, 91, 85, 89, 90, 83)	**35.1 (19.1 to 55.7)**	**52.0 (32.0 to 71.6)**	**44.4 (25.7 to 64.7)**	**68.4 (48.5 to 83.4)**	**61.5 (41.0 to 78.5)**	**81.2 (65.3 to 91.0)**	**76.1 (58.1 to 88.0)**
Day 14 (n=84, 91, 88, 90, 90, 92, 78)	**27.1 (14.7 to 44.6)**	**42.7 (25.7 to 61.7)**	**35.5 (20.4 to 54.0)**	**59.8 (40.9 to 76.3)**	**52.4 (33.9 to 70.2)**	**74.9 (58.0 to 86.6)**	**66.7 (50.7 to 82.5)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Forced Expiratory Volume in One Second at 12 Hours on Days 1 and 14 of Treatment

16. Secondary: Percentage of the Maximal Response of NVA237 Doses on Peak Forced Expiratory Volume in One Second on Days 1, 7 and 14 of Treatment [Time Frame: Days 1, 7, and 14]

Measure Type	Secondary
	Percentage of the Maximal Response of NVA237 Doses on Peak Forced Expiratory Volume in One Second on Days 1, 7 and 14

Measure Title	of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Peak FEV1 is the maximum FEV1 recorded in a pre-determined period of time. Percentage of the maximal response of NVA237 doses on Peak FEV1 was measured on days 1, 7 and 14 of treatment. Peak FEV1 was measured in response to all doses administered (see Outcome Measure #32). All FEV1 responses to active doses were corrected using the placebo response. A modeled dose response curve was fit to the placebo-corrected data, and extrapolated to estimate the maximal response. All FEV1 data are reported as a percentage of the theoretical maximal response.
Time Frame	Days 1, 7, and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	89	94	93	92	96	96	86
Percentage of the Maximal Response of NVA237 Doses on Peak Forced Expiratory Volume in One Second on Days 1, 7 and 14 of Treatment [units: Percentage of maximal response] Mean (90% Confidence Interval)							
Day 1 (n=89, 94, 93, 91, 96, 96, 86)	61.7 (47.4 to 74.7)	76.0 (62.5 to 85.5)	68.9 (54.1 to 81.1)	86.1 (75.8 to 92.2)	81.3 (68.7 to 89.6)	92.3 (85.6 to 96.0)	89.5 (80.6 to 94.5)
Day 7 (n=87, 93, 90, 92, 95, 94, 85)	53.3 (41.2 to 65.5)	69.2 (56.7 to 79.2)	61.1 (48.2 to 73.4)	81.5 (71.1 to 88.4)	75.6 (63.4 to 84.7)	89.6 (82.4 to 93.9)	85.8 (76.5 to 91.7)
Day 14 (n=86, 92, 91, 91, 95, 93, 84)	53.3 (41.2 to 65.5)	69.2 (56.7 to 79.2)	61.1 (48.2 to 73.4)	81.5 (71.1 to 88.4)	75.6 (63.4 to 84.7)	89.6 (82.4 to 93.9)	85.8 (76.5 to 91.7)

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Peak Forced Expiratory Volume in One Second on Days 1, 7 and 14 of Treatment

17. Secondary: Percentage of the Maximal Response of NVA237 Doses on Trough Forced Vital Capacity on Days 1, 7 and 14 [Time Frame: Days 1, 7 and 14]

Measure Type	Secondary
Measure Title	Percentage of the Maximal Response of NVA237 Doses on Trough Forced Vital Capacity on Days 1, 7 and 14
Measure Description	Percentage of the maximal response of NVA237 Doses on Trough Forced Vital Capacity (FVC) on Days 1, 7 and 14. FVC is the

	amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. Trough FVC was assessed via spirometry. (see Outcome Measure #33). Trough FVC is defined as the mean of the FVC values measured at 23 hours 15 mins and 23 hours 45 mins post-dose.
Time Frame	Days 1, 7 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.
Number of Participants Analyzed [units: participants]	**88**	**92**	**91**	**91**	**95**	**94**	**87**

Percentage of the Maximal Response of NVA237 Doses on Trough Forced Vital Capacity on Days 1, 7 and 14 [units: Percentage of maximal response] Mean (90% Confidence Interval)							
Day 1 (n=88, 92, 91, 90, 94, 94, 87)	**22.8 (11.3 to 43.5)**	**36.8 (19.6 to 60.9)**	**52.9 (26.2 to 79.9)**	**53.4 (30.7 to 75.8)**	**68.7 (38.3 to 88.9)**	**69.1 (43.4 to 86.3)**	**81.0 (52.3 to 94.1)**
Day 7 (n=87, 92, 90, 91, 95, 93, 85, 87)	**23.3 (11.2 to 45.2)**	**37.4 (19.6 to 62.5)**	**53.6 (26.3 to 81.2)**	**54.0 (30.7 to 77.1)**	**69.3 (38.3 to 89.7)**	**69.7 (43.3 to 87.1)**	**81.4 (52.0 to 94.6)**
Day 14 (n= 85, 90, 91, 88, 94, 93, 81, 84)	**23.3 (11.3 to 45.3)**	**37.4 (19.7 to 65.5)**	**53.6 (26.4 to 81.2)**	**54.0 (30.8 to 77.1)**	**69.3 (38.5 to 89.7)**	**69.7 (43.5 to 87.2)**	**81.4 (52.2 to 94.6)**

No statistical analysis provided for Percentage of the Maximal Response of NVA237 Doses on Trough Forced Vital Capacity on Days 1, 7 and 14

18. Secondary: Mean Daily Use of Rescue Medication by Treatment at Different Time Points [Time Frame: Baseline, Weeks 1, 2, 3 and 4]

Measure Type	Secondary
Measure Title	Mean Daily Use of Rescue Medication by Treatment at Different Time Points
Measure Description	Mean daily use of rescue medication by treatment and time points. Baseline was defined as the average of the total number of puffs of rescue medication during the week prior to treatment start, divided by the total number of days with non-missing rescue data during that week, then puffs were counted during weeks 1, 2, 3 and 4 postdose.
Time Frame	Baseline, Weeks 1, 2, 3 and 4
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.

Only patients with a non-missing value at both period baseline and the respective post-baseline visit were included. The modeling approach is not suitable for these data as the modeling assumptions do not hold.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**89**	**95**	**95**	**92**	**96**	**96**	**86**	**91**
Mean Daily Use of Rescue Medication by Treatment at Different Time Points [units: Number of Puffs] Mean (Standard Deviation)								
Baseline (n=89, 95, 95, 92, 96, 96, 86, 91)	**4.16 (3.131)**	**4.16 (2.925)**	**3.83 (3.218)**	**4.45 (3.068)**	**3.47 (2.996)**	**4.81 (3.276)**	**4.25 (3.613)**	**4.62 (3.710)**
Week 1 (n=89, 95, 95, 91, 96, 96, 86, 90)	**2.41**	**2.23**	**2.10**	**2.36**	**2.13**	**2.53**	**2.54**	**2.94**

	(2.338)	(2.158)	(2.337)	(2.291)	(2.349)	(2.609)	(2.678)	(3.075)
Week 2 (n=86, 94, 94, 91, 95, 93, 84, 89)	2.74 (2.784)	2.20 (2.054)	2.22 (2.541)	2.38 (2.541)	2.08 (2.568)	2.59 (2.658)	2.82 (3.003)	3.32 (3.455)
Week 3 (n= 86, 93, 94, 89, 93, 93, 83, 87)	2.75 (2.736)	2.40 (2.316)	2.29 (2.354)	2.37 (2.580)	2.23 (2.743)	2.75 (2.868)	2.69 (2.977)	3.34 (3.660)
Week 4 (n=86, 92, 94, 88, 93, 93, 82, 85)	2.91 (2.968)	2.52 (2.476)	2.42 (2.773)	2.46 (2.504)	2.32 (2.990)	2.65 (2.828)	2.78 (2.899)	3.41 (3.761)

No statistical analysis provided for Mean Daily Use of Rescue Medication by Treatment at Different Time Points

19. Other Pre-specified: Trough Forced Expiratory Volume in One Second by Treatment at Day 28 [Time Frame: Day 28]

Measure Type	Other Pre-specified
Measure Title	Trough Forced Expiratory Volume in One Second by Treatment at Day 28
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Spirometry was performed according to internationally accepted standards. Trough FEV1 was defined as the mean of the 23 hour 15 minute and 23 hour 45 minute post-dose values.
Time Frame	Day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 ug q.d.	NVA237 25 ug once daily
NVA237 25 ug q.d.	NVA237 12.5 ug once daily
NVA237 12.5 ug b.i.d.	NVA237 12.5 ug twice daily
NVA237 50 ug q.d.	NVA237 50 ug once daily
NVA237 25 ug b.i.d.	NVA237 25 ug twice daily
NVA237 100 ug q.d.	NVA237 100 ug once daily
NVA237 50 ug b.i.d.	NVA237 50 ug twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 ug q.d.	NVA237 25 ug q.d.	NVA237 12.5 ug b.i.d.	NVA237 50 ug q.d.	NVA237 25 ug b.i.d.	NVA237 100 ug q.d.	NVA237 50 ug b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**81**	**88**	**90**	**88**	**87**	**90**	**81**	**82**
Trough Forced Expiratory Volume in One Second by Treatment at Day 28 [units: Liters] Mean (Standard Deviation)	**1.319 (0.505)**	**1.368 (0.436)**	**1.354 (0.484)**	**1.340 (0.400)**	**1.384 (0.472)**	**1.410 (0.522)**	**1.493 (0.449)**	**1.268 (0.483)**

No statistical analysis provided for Trough Forced Expiratory Volume in One Second by Treatment at Day 28

20. Other Pre-specified: Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours at Day 28 of Treatment [Time Frame: 5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28]

Measure Type	Other Pre-specified

Measure Title	Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours at Day 28 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Spirometry was performed according to internationally accepted standards. FEV1 Area Under the Curve (AUC) measurements were taken at 5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28. FEV1 AUC was calculated as the sum of trapezoids divided by the length of time.
Time Frame	5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	82	90	91	90	92	91	82	82
Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours at Day 28 of Treatment [units: Liters] Mean (Standard Deviation)	1.307 (0.469)	1.351 (0.392)	1.321 (0.469)	1.317 (0.390)	1.339 (0.462)	1.395 (0.496)	1.457 (0.453)	1.247 (0.467)

No statistical analysis provided for Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours at Day 28 of Treatment

21. Other Pre-specified: Forced Expiratory Volume in One Second Area Under the Curve at Different Time Points (0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours) [Time Frame: 5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in One Second Area Under the Curve at Different Time Points (0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours)
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Spirometry was performed according to internationally accepted standards. FEV1 Area Under the Curve (AUC) measurements were taken at: 5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose). FEV1 AUC was calculated as the sum of trapezoids divided by the length of time.
Time Frame	5 min,15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on day 28
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.

Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**82**	**90**	**91**	**90**	**92**	**91**	**82**	**82**
Forced Expiratory Volume in One Second Area Under the Curve at Different Time Points (0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours) [units: Liters] Mean (Standard Deviation)								
AUC 0-4h (n=82,90,91,89,92,91,82,82)	**1.415 (0.494)**	**1.478 (0.439)**	**1.414 (0.489)**	**1.431 (0.411)**	**1.417 (0.487)**	**1.490 (0.532)**	**1.553 (0.504)**	**1.315 (0.490)**

AUC 0-8h (n=82,90,91,90,92,91,82,82)	**1.386 (0.477)**	**1.447 (0.423)**	**1.392 (0.491)**	**1.397 (0.411)**	**1.397 (0.476)**	**1.461 (0.520)**	**1.527 (0.495)**	**1.305 (0.485)**
AUC 0-12h (n=82,90,91,90,92,91,82,82)	**1.364 (0.480)**	**1.416 (0.416)**	**1.362 (0.487)**	**1.377 (0.408)**	**1.375 (0.469)**	**1.442 (0.515)**	**1.505 (0.480)**	**1.285 (0.476)**
AUC 12-24h (n=82,90,91,89,92,91,81,82)	**1.251 (0.464)**	**1.287 (0.382)**	**1.280 (0.458)**	**1.264 (0.378)**	**1.299 (0.459)**	**1.350 (0.480)**	**1.421 (0.426)**	**1.208 (0.461)**

No statistical analysis provided for Forced Expiratory Volume in One Second Area Under the Curve at Different Time Points (0-4 Hours, 0-8 Hours, 0-12 Hours, 12-24 Hours)

22. Other Pre-specified: Forced Expiratory Volume in One Second at 12 Hours on Day 28 of Treatment [Time Frame: 12 hours on day 28]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in One Second at 12 Hours on Day 28 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Spirometry was performed according to internationally accepted standards.
Time Frame	12 hours on day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description

NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**79**	**88**	**91**	**85**	**87**	**88**	**78**	**80**
Forced Expiratory Volume in One Second at 12 Hours on Day 28 of Treatment [units: Liters] Mean (Standard Deviation)	**1.272 (0.471)**	**1.330 (0.415)**	**1.279 (0.476)**	**1.330 (0.384)**	**1.320 (0.466)**	**1.391 (0.498)**	**1.429 (0.449)**	**1.256 (0.472)**

No statistical analysis provided for Forced Expiratory Volume in One Second at 12 Hours on Day 28 of Treatment

23. Other Pre-specified: Peak Forced Expiratory Volume in One Second at Day 28 of Treatment [Time Frame: 25 min , 15 min pre-dose, 5 min, 15 min, 1 , 2 ,3 , 4 , 6 , 8 , 10 hours , 11 hour 55 min and 14 hour post-dose on day 28]

Measure Type	Other Pre-specified
Measure Title	Peak Forced Expiratory Volume in One Second at Day 28 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by

	a spirometer. Spirometry was performed according to internationally accepted standards. Peak FEV1 is the maximum FEV1 recorded in a pre-determined period of time. Measurements were taken at 25 min , 15 min pre-dose, 5 min, 15 min, 1 , 2 ,3 , 4 , 6 , 8 , 10 hours , 11 hour 55 min and 14 hour post-dose on day 28.
Time Frame	25 min , 15 min pre-dose, 5 min, 15 min, 1 , 2 ,3 , 4 , 6 , 8 , 10 hours , 11 hour 55 min and 14 hour post-dose on day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed								

[units: participants]	**82**	**90**	**91**	**89**	**92**	**91**	**82**	**82**
Peak Forced Expiratory Volume in One Second at Day 28 of Treatment [units: Liters] Mean (Standard Deviation)	**1.500 (0.516)**	**1.563 (0.453)**	**1.494 (0.507)**	**1.514 (0.432)**	**1.504 (0.516)**	**1.570 (0.546)**	**1.630 (0.513)**	**1.397 (0.515)**

No statistical analysis provided for Peak Forced Expiratory Volume in One Second at Day 28 of Treatment

24. Other Pre-specified: Trough Forced Vital Capacity After 28 Days of Treatment [Time Frame: 23 hours 15 mins and 23 hours 45 mins post-dose on Day 28]

Measure Type	Other Pre-specified
Measure Title	Trough Forced Vital Capacity After 28 Days of Treatment
Measure Description	Forced Vital Capacity (FVC) after 28 days of treatment. FVC is the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. FVC was assessed via spirometry. Trough FVC was defined as the mean of the FVC values measured at 23 hours 15 mins and 23 hours 45 mins post-dose.
Time Frame	23 hours 15 mins and 23 hours 45 mins post-dose on Day 28
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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily

NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**81**	**88**	**90**	**88**	**87**	**90**	**81**	**82**
Trough Forced Vital Capacity After 28 Days of Treatment [units: Liters] Mean (Standard Deviation)	**2.939 (0.878)**	**3.007 (0.910)**	**2.954 (0.849)**	**2.973 (0.825)**	**3.041 (0.770)**	**2.974 (0.999)**	**3.080 (0.913)**	**2.703 (0.857)**

No statistical analysis provided for Trough Forced Vital Capacity After 28 Days of Treatment

25. Other Pre-specified: Trough Forced Expiratory Volume in One Second at Days 1, 7 and 14 [Time Frame: 23 hours 15 mins and 23 hours 45 mins post-dose on Days 1, 7 and 14]

Measure Type	Other Pre-specified
Measure Title	Trough Forced Expiratory Volume in One Second at Days 1, 7 and 14
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Spirometry was performed according to internationally accepted standards. Trough FEV1 was measured on Days 1, 7 and 14 of treatment. Trough FEV1 was defined as the mean of the FEV1 values

	measured at 23 hours 15 mins and 23 hours 45 mins post-dose.
Time Frame	23 hours 15 mins and 23 hours 45 mins post-dose on Days 1, 7 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	**NVA237 25.0 µg q.d.**	**NVA237 12.5 µg b.i.d.**	**NVA237 50.0 µg q.d.**	**NVA237 25.0 µg b.i.d.**	**NVA237 100.0 µg q.d.**	**NVA237 50.0 µg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**88**	**92**	**91**	**91**	**95**	**94**	**87**	**87**

Trough Forced Expiratory Volume in One Second at Days 1, 7 and 14 [units: Liters] Mean (Standard Deviation)								
Day 1 (n= 88,92,91, 90, 94, 94, 87, 86)	**1.299 (0.490)**	**1.387 (0.477)**	**1.375 (0.477)**	**1.371 (0.406)**	**1.355 (0.503)**	**1.367 (0.514)**	**1.492 (0.483)**	**1.290 (0.471)**
Day 7 (n= 87,92,90, 91, 95, 93, 85, 87)	**1.332 (0.499)**	**1.422 (0.432)**	**1.349 (0.467)**	**1.391 (0.392)**	**1.375 (0.486)**	**1.372 (0.501)**	**1.480 (0.474)**	**1.294 (0.491)**
Day 14 (n= 85,90,91, 88, 94, 93, 81, 84)	**1.336 (0.442)**	**1.349 (0.446)**	**1.335 (0.444)**	**1.356 (0.391)**	**1.359 (0.479)**	**1.375 (0.519)**	**1.500 (0.455)**	**1.284 (0.471)**

No statistical analysis provided for Trough Forced Expiratory Volume in One Second at Days 1, 7 and 14

26. Other Pre-specified: Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours on Days 1 and 14 of Treatment [Time Frame: 5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on days 1 and 14]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours on Days 1 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Spirometry was performed according to internationally accepted standards. FEV1 Area Under the Curve (AUC) measurements were taken at 5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on days 1 and 14 of treatment. FEV1 AUC was calculated as the sum of trapezoids divided by the length of time.
Time Frame	5 min, 15 min, 1,2,3,4,6,8,10 hours, 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on days 1 and 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.

Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**92**	**96**	**96**	**87**	**90**
Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours on Days 1 and 14 of Treatment [units: Liters] Mean (Standard Deviation)								
Day 1 (n= 89,94,93,92,96,96,87,90)	**1.318 (0.470)**	**1.370 (0.444)**	**1.354 (0.462)**	**1.361 (0.393)**	**1.336 (0.460)**	**1.376 (0.526)**	**1.466 (0.471)**	**1.256 (0.469)**

Day 14 (n= 86,92,91,91,95,93,84,86)	**1.306 (0.427)**	**1.353 (0.420)**	**1.324 (0.430)**	**1.348 (0.372)**	**1.335 (0.460)**	**1.386 (0.493)**	**1.449 (0.453)**	**1.253 (0.473)**

No statistical analysis provided for Forced Expiratory Volume in One Second Area Under the Curve 0-24 Hours on Days 1 and 14 of Treatment

27. Other Pre-specified: Forced Expiratory Volume in One Second Area Under the Curve 0-4 Hours on Days 1, 7 and 14 of Treatment [Time Frame: 5 min,15 min, 1,2,3,4 hours (postdose) on Days 1, 7 and 14]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in One Second Area Under the Curve 0-4 Hours on Days 1, 7 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Spirometry was performed according to internationally accepted standards. FEV1 Area Under the Curve (AUC) measurements were taken at 5 min, 15 min, 1,2,3,4 hours (postdose) on days 1, 7 and 14 of treatment. FEV1 AUC was calculated as the sum of trapezoids divided by the length of time.
Time Frame	5 min,15 min, 1,2,3,4 hours (postdose) on Days 1, 7 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily

NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**92**	**96**	**96**	**86**	**89**
Forced Expiratory Volume in One Second Area Under the Curve 0-4 Hours on Days 1, 7 and 14 of Treatment [units: Liters] Mean (Standard Deviation)								
Day 1 (n=89,94,93,91,96,96,86,89)	**1.428 (0.492)**	**1.483 (0.485)**	**1.421 (0.489)**	**1.469 (0.428)**	**1.411 (0.483)**	**1.453 (0.551)**	**1.533 (0.501)**	**1.312 (0.494)**
Day 7 (n=87,93,90,92,95,94,85,89)	**1.403 (0.468)**	**1.483 (0.463)**	**1.397 (0.478)**	**1.432 (0.407)**	**1.390 (0.472)**	**1.453 (0.505)**	**1.537 (0.494)**	**1.310 (0.491)**
Day 14 (n=86,92,91,91,95,93,84,86)	**1.451 (0.456)**	**1.473 (0.456)**	**1.390 (0.471)**	**1.468 (0.409)**	**1.429 (0.503)**	**1.460 (0.514)**	**1.545 (0.485)**	**1.314 (0.500)**

No statistical analysis provided for Forced Expiratory Volume in One Second Area Under the Curve 0-4 Hours on Days 1, 7 and 14 of Treatment

28. Other Pre-specified: Forced Expiratory Volume in One Second of Area Under the Curve 0-8 Hours Days 1, 7, and 14 [Time Frame: at 5 min,15 min, 1,2,3,4,6,8 hours (postdose) on days 1, 7 and 14]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in One Second of Area Under the Curve 0-8 Hours Days 1, 7, and 14
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on FEV1 Area Under the Curve (AUC) 0-8 was calculated from measurements taken at 5 min,15 min, 1,2,3,4,6,8 hours (postdose) on days 1, 7, and 14. FEV1 AUC was calculated as the sum of trapezoids divided by the length of time.
Time Frame	at 5 min,15 min, 1,2,3,4,6,8 hours (postdose) on days 1, 7 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	89	94	93	92	96	96	87	90
Forced Expiratory Volume in One Second of Area Under the Curve 0-8 Hours Days 1, 7, and 14 [units: Liters] Mean (Standard Deviation)								
Day 1 (n=89, 94, 93, 91, 96, 96, 87, 90)	1.400 (0.486)	1.450 (0.476)	1.401 (0.483)	1.451 (0.426)	1.390 (0.476)	1.446 (0.548)	1.519 (0.493)	1.301 (0.488)
Day 7 (n= 87, 93, 91, 92, 95, 94, 85, 89)	1.386 (0.471)	1.462 (0.455)	1.375 (0.464)	1.409 (0.397)	1.373 (0.470)	1.433 (0.503)	1.516 (0.481)	1.293 (0.489)
Day 14 (n=86, 92, 91, 91, 95, 93, 84, 86)	1.381 (0.453)	1.441 (0.452)	1.375 (0.463)	1.435 (0.398)	1.400 (0.486)	1.442 (0.508)	1.514 (0.479)	1.293 (0.498)

No statistical analysis provided for Forced Expiratory Volume in One Second of Area Under the Curve 0-8 Hours Days 1, 7, and 14

29. Other Pre-specified: Forced Expiratory Volume in One Second Area Under the Curve 0-12 Hours at Day 1 and 14 of Treatment [Time Frame: 5 min,15 min, 1,2,3,4,6,8,10 hours, 11h 55 min (postdose) on days 1 and 14]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in One Second Area Under the Curve 0-12 Hours at Day 1 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses was calculated on FEV1 Area Under the Curve (AUC) 0-12 hours from measurements taken at at 5 min,15 min, 1,2,3,4,6,8,10 hours, 11h 55 min (postdose) on days 1 and 14. FEV1 AUC

	was calculated as the sum of trapezoids divided by the length of time.
Time Frame	5 min,15 min, 1,2,3,4,6,8,10 hours, 11h 55 min (postdose) on days 1 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**91**	**96**	**96**	**87**	**90**
Forced Expiratory Volume in One Second Area								

Under the Curve 0-12 Hours at Day 1 and 14 of Treatment [units: Liters] Mean (Standard Deviation)								
Day 1 (n=89, 94, 93, 91, 96, 96, 87, 90)	**1.382 (0.488)**	**1.425 (0.465)**	**1.379 (0.474)**	**1.430 (0.421)**	**1.364 (0.470)**	**1.431 (0.544)**	**1.498 (0.484)**	**1.289 (0.482)**
Day 14 (n=86, 92, 91, 91, 95, 93, 84, 86)	**1.360 (0.447)**	**1.416 (0.445)**	**1.357 (0.452)**	**1.406 (0.388)**	**1.378 (0.480)**	**1.427 (0.503)**	**1.494 (0.472)**	**1.281 (0.493)**

No statistical analysis provided for Forced Expiratory Volume in One Second Area Under the Curve 0-12 Hours at Day 1 and 14 of Treatment

30. Other Pre-specified: Forced Expiratory Volume in One Second of Area Under the Curve 12-24 Hours Over Days 1, and 14 of Treatment [Time Frame: 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on Days 1 and 14]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in One Second of Area Under the Curve 12-24 Hours Over Days 1, and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 on FEV1 Area under the curve (AUC) 12-24 hours was calculated from measurements taken at 11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on Days 1 and 14. FEV1 AUC was calculated as the sum of trapezoids divided by the length of time.
Time Frame	11 hours 55 min, 14,20,22 hours; 23 hours 15 min, 23 hours 45 min (postdose) on Days 1 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**92**	**96**	**96**	**87**	**90**
Forced Expiratory Volume in One Second of Area Under the Curve 12-24 Hours Over Days 1, and 14 of Treatment [units: Liters] Mean (Standard Deviation)								
Day 1 (n=89, 94, 93, 92, 96, 96, 87, 90)	**1.257 (0.459)**	**1.315 (0.432)**	**1.329 (0.455)**	**1.295 (0.375)**	**1.306 (0.454)**	**1.322 (0.512)**	**1.437 (0.461)**	**1.224 (0.459)**
Day 14 (n= 86, 92, 91, 91, 95, 93, 84, 86)	**1.251 (0.417)**	**1.289 (0.405)**	**1.290 (0.415)**	**1.291 (0.366)**	**1.291 (0.450)**	**1.344 (0.488)**	**1.406 (0.437)**	**1.225 (0.459)**

No statistical analysis provided for Forced Expiratory Volume in One Second of Area Under the Curve 12-24 Hours Over Days 1, and 14 of Treatment

31. Other Pre-specified: Forced Expiratory Volume in One Second at 12 Hours on Days 1 and 14 of Treatment [Time Frame: Days 1 and 14]

Measure Type	Other Pre-specified
Measure Title	Forced Expiratory Volume in One Second at 12 Hours on Days 1 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Percentage of the maximal response of NVA237 doses on FEV1 at 12 hours was measured on days 1 and 14.
Time Frame	Days 1 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	84	91	91	90	90	92	83	83
Forced Expiratory Volume in One Second at 12 Hours on Days 1 and 14 of Treatment [units: Liters] Mean (Standard Deviation)								
Day 1 (n=83, 90, 91, 85, 89, 90, 83, 81)	1.319 (0.502)	1.364 (0.452)	1.327 (0.465)	1.345 (0.405)	1.299 (0.457)	1.374 (0.549)	1.439 (0.459)	1.244 (0.449)
Day 14 (n=84, 91, 88, 90, 90, 92, 78, 83)	1.290 (0.431)	1.356 (0.431)	1.303 (0.428)	1.329 (0.368)	1.329 (0.455)	1.389 (0.506)	1.469 (0.436)	1.268 (0.477)

No statistical analysis provided for Forced Expiratory Volume in One Second at 12 Hours on Days 1 and 14 of Treatment

32. Other Pre-specified: Peak Forced Expiratory Volume in One Second on Days 1, 7 and 14 of Treatment [Time Frame: Days 1, 7, and 14]

Measure Type	Other Pre-specified
Measure Title	Peak Forced Expiratory Volume in One Second on Days 1, 7 and 14 of Treatment
Measure Description	Forced Expiratory Volume in one second (FEV1) is calculated as the volume of air forcibly exhaled in one second as measured by a spirometer. Peak FEV1 is the maximum FEV1 recorded in a pre-determined period of time. Percentage of the maximal response of NVA237 doses on Peak FEV1 was measured on days 1, 7 and 14 of treatment.
Time Frame	Days 1, 7, and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily
NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	**NVA237 25.0 µg q.d.**	**NVA237 12.5 µg b.i.d.**	**NVA237 50.0 µg q.d.**	**NVA237 25.0 µg b.i.d.**	**NVA237 100.0 µg q.d.**	**NVA237 50.0 µg b.i.d.**	**Placebo**
Number of Participants Analyzed [units: participants]	**89**	**94**	**93**	**92**	**96**	**96**	**86**	**89**
Peak Forced Expiratory Volume in One Second on Days 1, 7 and 14 of Treatment [units: Liters] Mean (Standard Deviation)								
Day 1 (n=89, 94, 93, 91, 96, 96, 86, 89)	**1.503 (0.515)**	**1.558 (0.497)**	**1.494 (0.507)**	**1.541 (0.442)**	**1.483 (0.495)**	**1.521 (0.567)**	**1.597 (0.510)**	**1.378 (0.504)**

Day 7 (n=87, 93, 90, 92, 95, 94, 85, 89)	**1.459 (0.477)**	**1.540 (0.474)**	**1.455 (0.496)**	**1.501 (0.426)**	**1.448 (0.491)**	**1.513 (0.524)**	**1.598 (0.510)**	**1.364 (0.504)**
Day 14 (n=86, 92, 91, 91, 95, 93, 84, 86)	**1.487 (0.471)**	**1.547 (0.465)**	**1.465 (0.484)**	**1.537 (0.429)**	**1.506 (0.513)**	**1.528 (0.529)**	**1.615 (0.497)**	**1.380 (0.509)**

No statistical analysis provided for Peak Forced Expiratory Volume in One Second on Days 1, 7 and 14 of Treatment

33. Other Pre-specified: Trough Forced Vital Capacity on Days 1, 7 and 14 [Time Frame: Days 1, 7 and 14]

Measure Type	Other Pre-specified
Measure Title	Trough Forced Vital Capacity on Days 1, 7 and 14
Measure Description	Trough Forced Vital Capacity (FVC) on Days 1, 7 and 14. FVC is the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. FVC was assessed via spirometry. (see Outcome Measure #23). Trough FVC was defined as the mean of the 23 hour 15 minute and 23 hour 45 minute post-dose values.
Time Frame	Days 1, 7 and 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.
Full analysis set includes all randomized patients who received at least one dose of study drug and data available for analysis. Only patients with non-missing values were included.

Reporting Groups

	Description
NVA237 12.5 µg q.d.	NVA237 12.5 µg once daily

NVA237 25.0 µg q.d.	NVA237 25.0 µg once daily
NVA237 12.5 µg b.i.d.	NVA237 12.5 µg twice daily
NVA237 50.0 µg q.d.	NVA237 50.0 µg once daily
NVA237 25.0 µg b.i.d.	NVA237 25.0 µg twice daily
NVA237 100.0 µg q.d.	NVA237 100.0 µg once daily
NVA237 50.0 µg b.i.d.	NVA237 50.0 µg twice daily
Placebo	Placebo to NVA237 once daily

Measured Values

	NVA237 12.5 µg q.d.	NVA237 25.0 µg q.d.	NVA237 12.5 µg b.i.d.	NVA237 50.0 µg q.d.	NVA237 25.0 µg b.i.d.	NVA237 100.0 µg q.d.	NVA237 50.0 µg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**88**	**92**	**91**	**91**	**95**	**94**	**87**	**87**
Trough Forced Vital Capacity on Days 1, 7 and 14 [units: Liters] Mean (Standard Deviation)								
Day 1 (n=88, 92, 91, 90, 94, 94, 87, 86)	**2.895 (0.830)**	**3.063 (0.967)**	**2.997 (0.835)**	**3.017 (0.820)**	**2.956 (0.810)**	**2.944 (1.001)**	**3.088 (0.961)**	**2.779 (0.838)**
Day 7 (n=87, 92, 90, 91, 95, 93, 85, 87)	**2.982 (0.833)**	**3.135 (0.928)**	**2.991 (0.873)**	**3.072 (0.833)**	**2.993 (0.798)**	**2.977 (0.987)**	**3.114 (0.975)**	**2.759 (0.875)**
Day 14 (n= 85, 90, 91, 88, 94, 93, 81, 84)	**2.958 (0.772)**	**3.000 (0.934)**	**2.965 (0.862)**	**3.003 (0.812)**	**2.960 (0.763)**	**2.941 (0.987)**	**3.113 (0.941)**	**2.744 (0.841)**

No statistical analysis provided for Trough Forced Vital Capacity on Days 1, 7 and 14

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
NVA237 12.5 ug q.d.	NVA237 12.5 ug q.d.
NVA237 25 ug q.d.	NVA237 25 ug q.d.
NVA237 12.5 ug b.i.d.	NVA237 12.5 ug b.i.d.
NVA237 50 ug q.d.	NVA237 50 ug q.d.
NVA237 25 ug b.i.d.	NVA237 25 ug b.i.d.
NVA237 100 ug q.d.	NVA237 100 ug q.d.
NVA237 50 ug b.i.d.	NVA237 50 ug b.i.d.
Placebo	Placebo

Serious Adverse Events

	NVA237 12.5 ug q.d.	NVA237 25 ug q.d.	NVA237 12.5 ug b.i.d.	NVA237 50 ug q.d.	NVA237 25 ug b.i.d.	NVA237 100 ug q.d.	NVA237 50 ug b.i.d.	Placebo
Total, serious adverse events								
# participants affected / at risk	**2/89 (2.25%)**	**2/96 (2.08%)**	**1/96 (1.04%)**	**3/92 (3.26%)**	**4/96 (4.17%)**	**3/96 (3.13%)**	**1/87 (1.15%)**	**3/91 (3.30%)**
Cardiac disorders								
Angina pectoris †1								
# participants	**0/89 (0.00%)**	**0/96 (0.00%)**	**0/96 (0.00%)**	**0/92 (0.00%)**	**0/96 (0.00%)**	**0/96 (0.00%)**	**0/87 (0.00%)**	**1/91 (1.10%)**

affected / at risk								
Ventricular extrasystoles [†1]								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	1/87 (1.15%)	0/91 (0.00%)
Gastrointestinal disorders								
Gastrooesophageal reflux disease [†1]								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	1/96 (1.04%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
Pancreatitis acute [†1]								
# participants affected / at risk	0/89 (0.00%)	1/96 (1.04%)	0/96 (0.00%)	0/92 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
General disorders								
Non-cardiac chest pain [†1]								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	1/96 (1.04%)	1/96 (1.04%)	0/87 (0.00%)	0/91 (0.00%)
Sudden death [†1]								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	1/92 (1.09%)	0/96 (0.00%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
Infections and infestations								
Gastroenteritis [†1]								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	1/92 (1.09%)	0/96 (0.00%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
Herpes zoster [†1]								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/87 (0.00%)	1/91 (1.10%)
Pneumonia [†1]								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	1/96 (1.04%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
Respiratory tract infection [†1]								

# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/87 (0.00%)	1/91 (1.10%)
Injury, poisoning and procedural complications								
Incisional hernia †1								
# participants affected / at risk	0/89 (0.00%)	1/96 (1.04%)	0/96 (0.00%)	0/92 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
Injury †1								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	1/96 (1.04%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
Nervous system disorders								
Cerebrovascular accident †1								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	1/92 (1.09%)	0/96 (0.00%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
Reproductive system and breast disorders								
Epididymitis †1								
# participants affected / at risk	1/89 (1.12%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/87 (0.00%)	0/91 (0.00%)
Respiratory, thoracic and mediastinal disorders								
Chronic obstructive pulmonary disease †1								
# participants affected / at risk	1/89 (1.12%)	0/96 (0.00%)	1/96 (1.04%)	0/92 (0.00%)	2/96 (2.08%)	1/96 (1.04%)	0/87 (0.00%)	0/91 (0.00%)
Vascular disorders								
Hypertensive crisis †1								
# participants affected / at risk	0/89 (0.00%)	0/96 (0.00%)	0/96 (0.00%)	0/92 (0.00%)	0/96 (0.00%)	1/96 (1.04%)	0/87 (0.00%)	0/91 (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 q.d.	NVA237 12.5 ug q.d.
NVA237 25 ug q.d.	NVA237 25 ug q.d.
NVA237 12.5 ug b.i.d.	NVA237 12.5 ug b.i.d.
NVA237 50 ug q.d.	NVA237 50 ug q.d.
NVA237 25 ug b.i.d.	NVA237 25 ug b.i.d.
NVA237 100 ug q.d.	NVA237 100 ug q.d.
NVA237 50 ug b.i.d.	NVA237 50 ug b.i.d.
Placebo	Placebo

Other Adverse Events

	NVA237 12.5 ug q.d.	NVA237 25 ug q.d.	NVA237 12.5 ug b.i.d.	NVA237 50 ug q.d.	NVA237 25 ug b.i.d.	NVA237 100 ug q.d.	NVA237 50 ug b.i.d.	Placebo
Total, other (not including serious)								

adverse events								
# participants affected / at risk	**9/89 (10.11%)**	**11/96 (11.46%)**	**5/96 (5.21%)**	**7/92 (7.61%)**	**8/96 (8.33%)**	**9/96 (9.38%)**	**9/87 (10.34%)**	**14/91 (15.38%)**
Infections and infestations								
Nasopharyngitis †1								
# participants affected / at risk	**4/89 (4.49%)**	**8/96 (8.33%)**	**2/96 (2.08%)**	**4/92 (4.35%)**	**3/96 (3.13%)**	**4/96 (4.17%)**	**5/87 (5.75%)**	**6/91 (6.59%)**
Nervous system disorders								
Headache †1								
# participants affected / at risk	**1/89 (1.12%)**	**1/96 (1.04%)**	**2/96 (2.08%)**	**3/92 (3.26%)**	**3/96 (3.13%)**	**4/96 (4.17%)**	**3/87 (3.45%)**	**6/91 (6.59%)**
Respiratory, thoracic and mediastinal disorders								
Chronic obstructive pulmonary disease †1								
# participants affected / at risk	**6/89 (6.74%)**	**3/96 (3.13%)**	**1/96 (1.04%)**	**0/92 (0.00%)**	**3/96 (3.13%)**	**2/96 (2.08%)**	**1/87 (1.15%)**	**4/91 (4.40%)**

† 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 or disclosure of trial results in their entirety.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 41 61 324 1111

No publications provided by Novartis

Publications automatically indexed to this study:

Arievich H, Overend T, Renard D, Gibbs M, Alagappan V, Looby M, Banerji D. A novel model-based approach for dose determination of glycopyrronium bromide in COPD. BMC Pulm Med. 2012 Dec 8;12:74. doi: 10.1186/1471-2466-12-74.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01119950 History of Changes
Other Study ID Numbers:	**CNVA237A2208** 2009-014038-11 (EudraCT Number)
Study First Received:	May 5, 2010
Results First Received:	January 23, 2013
Last Updated:	March 3, 2015
Health Authority:	United States: Food and Drug Administration Belgium: Federal Agency for Medicinal Products and Health Products Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy India: Central Drugs Standard Control Organization Netherlands: Medicines Evaluation Board (MEB) Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Spain: Agencia Española de Medicamentos y Productos Sanitarios Romania: National Medicines Agency