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Trial record **1 of 1** for: CNVA237A2310

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Effect of NVA237 on Exercise Endurance in Patients With Chronic Obstructive Pulmonary Disease (COPD) (GLOW3)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01154127

First received: June 29, 2010
Last updated: April 10, 2012
Last verified: April 2012
History of Changes

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Results First Received: February 8, 2012

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

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
NVA237 Followed by Placebo	Period 1: 50 µg NVA237 via NEOHALER inhaler device for 21 days. Period 2: Matching placebo via NEOHALER inhaler device for 21 days The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo Followed by NVA237	Period 1: Matching placebo of NVA237 via NEOHALER inhaler device for 21 days Period 2: 50 µg NVA237 via NEOHALER inhaler device for 21 days. The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Participant Flow for 3 periods

Period 1: Period 1 (21 Days)

	NVA237 Followed by Placebo	Placebo Followed by NVA237

STARTED	55	53
COMPLETED	52	47
NOT COMPLETED	3	6
Adverse Event	3	4
Withdrawal by Subject	0	2

Period 2: Washout (14 - 28 Days)

	NVA237 Followed by Placebo	Placebo Followed by NVA237
STARTED	52	47
COMPLETED	49	47
NOT COMPLETED	3	0
Adverse Event	2	0
Abnormal Test Procedure	1	0

Period 3: Period 2 (21 Days)

	NVA237 Followed by Placebo	Placebo Followed by NVA237
STARTED	49	47
COMPLETED	49	46
NOT COMPLETED	0	1
Protocol Deviation	0	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
NVA237 Followed by Placebo	Period 1: 50 µg NVA237 via NEOHALER inhaler device for 21 days. Period 2: Matching placebo via NEOHALER inhaler device for 21 days The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo Followed by NVA237	Period 1: Matching placebo of NVA237 via NEOHALER inhaler device for 21 days Period 2: 50 µg NVA237 via NEOHALER inhaler device for 21 days. The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Total	Total of all reporting groups

Baseline Measures

	NVA237 Followed by Placebo	Placebo Followed by NVA237	Total
Number of Participants [units: participants]	**55**	**53**	**108**
Age [units: years] Mean (Standard Deviation)	**61.3 (8.50)**	**59.7 (8.78)**	**60.5 (8.64)**
Gender [units: participants]			

Female	**25**	**20**	**45**
Male	**30**	**33**	**63**

Outcome Measures

Hide All Outcome Measures

1. Primary: Exercise Endurance Time During a Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks (Day 21) of Treatment [Time Frame: Day 21]

Measure Type	Primary
Measure Title	Exercise Endurance Time During a Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks (Day 21) of Treatment
Measure Description	SMETT is an exercise procedure where the patient cycles at 80% of the maximum workload (Wmax)value achieved at the Incremental exercise test. During this test, the patient will cycle at a constant load. Exercise endurance time was from commencement of loaded pedaling to stopping exercise. The analysis-of covariance model included the sequence, period, and treatment as fixed factors, the baseline value as covariate and the patient as a random effect.
Time Frame	Day 21
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.
Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day 21 of this period and had no major protocol deviation impacting the primary PD assessment.

Reporting Groups

	Description

NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed [units: participants]	**96**	**96**
Exercise Endurance Time During a Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks (Day 21) of Treatment [units: seconds] Least Squares Mean (95% Confidence Interval)	**505.63 (466.59 to 544.68)**	**416.70 (377.76 to 455.64)**

No statistical analysis provided for Exercise Endurance Time During a Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks (Day 21) of Treatment

2. Secondary: Isotime Inspiratory Capacity (IC) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks of Treatment [Time Frame: Day 21]

Measure Type	Secondary
Measure Title	Isotime Inspiratory Capacity (IC) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks of Treatment
Measure Description	Isotime is the last matching timepoint in the submaximal exercise tolerance test (SMETT) at which for both periods the

	patient has a test result. The analysis-of covariance model included the sequence, period, and treatment as fixed factors, the baseline value as covariate and the patient as a random effect.
Time Frame	Day 21
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.
Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day 21 of this period and had no major protocol deviation impacting primary the PD assessment.

Reporting Groups

	Description
NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed [units: participants]	**92**	**92**
Isotime Inspiratory Capacity (IC) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks of Treatment	**2.22**	**2.02**

[units: Liters] **Least Squares Mean (95% Confidence Interval)**	**(2.15 to 2.31)**	**(1.95 to 2.08)**

No statistical analysis provided for Isotime Inspiratory Capacity (IC) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks of Treatment

3. Secondary: Inspiratory Capacity (IC) at Rest (1 Hour Post Dose) and at Peak (End of Exercise) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks of Treatment [Time Frame: Day 21]

Measure Type	Secondary
Measure Title	Inspiratory Capacity (IC) at Rest (1 Hour Post Dose) and at Peak (End of Exercise) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks of Treatment
Measure Description	IC at peak was observed using spirometry. However, two different methodologies (whole body plethysmography (Bodybox) and spirometry) were used to observe IC at rest. The analysis of covariance model included the sequence, period, and treatment as fixed factors, the baseline value as covariate and the patient as a random effect.
Time Frame	Day 21
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.
Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day 21 of this period and had no major protocol deviation impacting the primary PD assessment. “n” indicates number of participants with observation at each time-point.

Reporting Groups

	Description

NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed [units: participants]	**99**	**96**
Inspiratory Capacity (IC) at Rest (1 Hour Post Dose) and at Peak (End of Exercise) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks of Treatment [units: Litres] Least Squares Mean (95% Confidence Interval)		
IC at peak (Spirometry), Day 21 (n = 93, 90)	**2.22 (2.16 to 2.28)**	**2.03 (1.97 to 2.10)**
IC at rest (Bodybox) Day 21 (n= 97, 96)	**2.49 (2.40 to 2.59)**	**2.26 (2.17 to 2.35)**
IC at rest (Spirometry), Day 21 (n= 98, 96)	**2.39 (2.33 to 2.45)**	**2.17 (2.10 to 2.23)**

No statistical analysis provided for Inspiratory Capacity (IC) at Rest (1 Hour Post Dose) and at Peak (End of Exercise) During Sub-maximal Constant-

load Cycle Ergometry Test (SMETT) After 3 Weeks of Treatment

4. Secondary: Peak and Trough (24 h Post Dose) Forced Expiratory Volume in 1 Second (FEV1) and Forced Vital Capacity (FVC) [Time Frame: Day 21]

Measure Type	Secondary
Measure Title	Peak and Trough (24 h Post Dose) Forced Expiratory Volume in 1 Second (FEV1) and Forced Vital Capacity (FVC)
Measure Description	FEV1 is the amount of air that can be exhaled in one second. FEV1 was measured with spirometry conducted according to internationally accepted standards. FVC is the volume of air that can forcibly be blown out after full inspiration and is used in spirometry tests. The trough effects of Day 1 treatment are derived from values prior to morning dosing on the next treatment day (Day 2 of the corresponding period). The analysis-of covariance model included the sequence, period, and treatment as fixed factors, the baseline value as covariate and the patient as a random effect.
Time Frame	Day 21
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.
Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day 21 of this period and had no major protocol deviation impacting the primary PD assessment.

Reporting Groups

	Description
NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was

	allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed [units: participants]	**99**	**96**
Peak and Trough (24 h Post Dose) Forced Expiratory Volume in 1 Second (FEV1) and Forced Vital Capacity (FVC) [units: Litres] Least Squares Mean (95% Confidence Interval)		
FEV1 at peak, Day 21	**1.60 (1.56 to 1.64)**	**1.35 (1.31 to 1.39)**
FEV1 at trough, Day 21	**1.44 (1.40 to 1.48)**	**1.33 (1.29 to 1.37)**
FVC at peak, Day 21	**3.37 (3.30 to 3.44)**	**3.00 (2.93 to 3.06)**
FVC at trough, Day 21	**3.17 (3.11 to 3.23)**	**2.96 (2.90 to 3.02)**

No statistical analysis provided for Peak and Trough (24 h Post Dose) Forced Expiratory Volume in 1 Second (FEV1) and Forced Vital Capacity (FVC)

5. Secondary: Slow Vital Capacity (SVC) and Total Lung Capacity (TLC) [Time Frame: Day 21]

Measure Type	Secondary
Measure Title	Slow Vital Capacity (SVC) and Total Lung Capacity (TLC)
Measure Description	Vital Capacity is the amount of air that can be forcibly exhaled from the lungs after a full inhalation. Slow Vital Capacity (SVC) test is performed by having the patient slowly and completely blow out all of the air from their lungs. Total Lung Capacity (TLC) is the best vital capacity plus residual volume. Whole body plethysmography (Bodybox) was used to measure SVC and TLC. The trough effects of Day 1 treatment are derived from values prior to morning dosing on the next treatment day (Day 2 of the corresponding period).
Time Frame	Day 21
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.
Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day 21 of this period and had no major protocol deviation impacting the primary PD assessment. “n” indicates number of participants with observation at each time-point.

Reporting Groups

	Description
NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed [units: participants]	**99**	**96**
Slow Vital Capacity (SVC) and Total Lung Capacity (TLC) [units: Litres] Least Squares Mean (95% Confidence Interval)		
SVC at trough, Day 21 (n= 98, 96)	**3.21 (3.14 to 3.27)**	**3.14 (3.07 to 3.21)**
SVC at peak, Day 21 (n= 97, 96)	**3.40 (3.33 to 3.47)**	**3.14 (3.07 to 3.21)**
TLC at trough, Day 21 (n= 98, 96)	**6.99 (6.88 to 7.09)**	**7.17 (7.07 to 7.28)**
TLC at peak, Day 21 (n= 97, 96)	**6.86 (6.75 to 6.97)**	**7.10 (6.99 to 7.21)**

No statistical analysis provided for Slow Vital Capacity (SVC) and Total Lung Capacity (TLC)

6. Secondary: Specific Airways Conductance (SGaw) [Time Frame: Day 21]

Measure Type	Secondary
Measure Title	Specific Airways Conductance (SGaw)

Measure Description	SGaw is a measure of how hard it is to get air into the lungs, measured by (Sec(-1)*kP). Whole body plethysmography (Bodybox) was used to measure SGaw. The analysis-of covariance model included the sequence, period, and treatment as fixed factors, the baseline value as covariate and the patient as a random effect.
Time Frame	Day 21
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.
Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day 21 of this period and had no major protocol deviation impacting the primary PD assessment.

Reporting Groups

	Description
NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed [units: participants]	**99**	**96**

Specific Airways Conductance (SGaw) [units: litres/(Second*kpa); kpa = kilopascal] Least Squares Mean (95% Confidence Interval)		
SGaw at trough, Day 21 (n= 98, 96)	**0.48 (0.45 to 0.51)**	**0.40 (0.38 to 0.43)**
SGaw at peak, Day 21 (n= 97, 96)	**0.66 (0.63 to 0.70)**	**0.42 (0.39 to 0.46)**

No statistical analysis provided for Specific Airways Conductance (SGaw)

7. Secondary: Exertional Dyspnea (Borg CR10 Scale) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks Treatment [Time Frame: Day 21]

Measure Type	Secondary
Measure Title	Exertional Dyspnea (Borg CR10 Scale) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks Treatment
Measure Description	The Borg CR10 Scale consists of 12-point score that the patients pointed to so as to indicate their level of dyspnea before and during exercise testing (where 0 indicates no breathlessness at all and 12 indicates maximum breathlessness). A reduction in this score indicates an improvement. The analysis-of covariance model included the sequence, period, and treatment as fixed factors, the baseline value as covariate and the patient as a random effect.
Time Frame	Day 21
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.
Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day

21 of this period and had no major protocol deviation impacting the primary PD assessment.

Reporting Groups

	Description
NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed **[units: participants]**	**93**	**93**
Exertional Dyspnea (Borg CR10 Scale) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks Treatment **[units: units on a scale]** **Least Squares Mean (95% Confidence Interval)**	**5.64** **(5.05 to 6.23)**	**6.80** **(6.20 to 7.39)**

No statistical analysis provided for Exertional Dyspnea (Borg CR10 Scale) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks Treatment

8. Secondary: Leg Discomfort (Borg CR10 Scale) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks Treatment
[Time Frame: Day 21]

Measure Type	Secondary
Measure Title	Leg Discomfort (Borg CR10 Scale) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks Treatment
Measure Description	The modified Borg CR10 Scale consists of 12-point score that the patients pointed to so as to indicate their level of leg discomfort before and during exercise testing (where 0 indicates no breathlessness at all and 12 indicates maximum breathlessness). A reduction in this score indicates an improvement. The analysis-of covariance model included the sequence, period, and treatment as fixed factors, the baseline value as covariate and the patient as a random effect.
Time Frame	Day 21
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.
Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day 21 of this period and had no major protocol deviation impacting the primary PD assessment.

Reporting Groups

	Description
NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed [units: participants]	**93**	**93**
Leg Discomfort (Borg CR10 Scale) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks Treatment [units: units on a scale] Least Squares Mean (95% Confidence Interval)	**6.21 (5.67 to 6.76)**	**7.05 (6.51 to 7.60)**

No statistical analysis provided for Leg Discomfort (Borg CR10 Scale) During Sub-maximal Constant-load Cycle Ergometry Test (SMETT) After 3 Weeks Treatment

9. Secondary: Exercise Endurance Time During a Sub-maximal Constant-load Cycle Ergometry Test (SMETT) on Treatment Day 1 [Time Frame: Day 1]

Measure Type	Secondary
Measure Title	Exercise Endurance Time During a Sub-maximal Constant-load Cycle Ergometry Test (SMETT) on Treatment Day 1
Measure Description	SMETT is an exercise procedure where the patient cycles at 80% of the maximum workload (Wmax)value achieved at the Incremental exercise test. During this test, the patient will cycle at a constant load. Exercise endurance time was from commencement of loaded pedaling to stopping exercise. The analysis-of covariance model included the sequence, period, and treatment as fixed factors, the baseline value as covariate and the patient as a random effect.
Time Frame	Day 1
Safety Issue	No

Population Description

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

Pharmacodynamics (PD) set consisted of participants who completed at least one treatment period, had an evaluable PD assessment on Day 21 of this period and had no major protocol deviation impacting the primary PD assessment.

Reporting Groups

	Description
NVA237	Participants received NVA237 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Participants received Placebo 50 µg once daily delivered via the NEOHALER inhaler device device for 3 weeks (21 days). The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Measured Values

	NVA237	Placebo
Number of Participants Analyzed [units: participants]	**96**	**94**
Exercise Endurance Time During a Sub-maximal Constant-load Cycle Ergometry Test (SMETT) on Treatment Day 1 [units: Seconds] Least Squares Mean (95% Confidence Interval)	**490.92 (458.45 to 523.38)**	**447.78 (415.09 to 480.48)**

No statistical analysis provided for Exercise Endurance Time During a Sub-maximal Constant-load Cycle Ergometry Test (SMETT) on Treatment Day 1

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	All patients as randomized who received at least one dose of study drug are included in the safety analysis set.

Reporting Groups

	Description
NVA237	Period 1: 50 µg NVA237 via NEOHALER inhaler device for 21 days Period 2: Matching placebo via NEOHALER inhaler device for 21 days The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Period 1: 50 µg NVA237 via NEOHALER inhaler device for 21 days Period 2: Matching placebo via NEOHALER inhaler device for 21 days The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Serious Adverse Events

	NVA237	Placebo
Total, serious adverse events		
# participants affected / at risk	**1/102 (0.98%)**	**0/102 (0.00%)**
Musculoskeletal and connective tissue disorders		
Intervertebral disc protrusion † 1		
# participants affected / at risk	**1/102 (0.98%)**	**0/102 (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	All patients as randomized who received at least one dose of study drug are included in the safety analysis set.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
NVA237	Period 1: 50 µg NVA237 via NEOHALER inhaler device for 21 days Period 2: Matching placebo via NEOHALER inhaler device for 21 days The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.
Placebo	Period 1: 50 µg NVA237 via NEOHALER inhaler device for 21 days Period 2: Matching placebo via NEOHALER inhaler device for 21 days The washout period ran for 14 to 28 days between treatment periods. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. Salbutamol (albuterol) was used as rescue medication throughout the study.

Other Adverse Events

	NVA237	Placebo
Total, other (not including serious) adverse events		

# participants affected / at risk	**0/102 (0.00%)**	**0/102 (0.00%)**

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: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Beeh KM, Singh D, Di Scala L, Drollmann A. Once-daily NVA237 improves exercise tolerance from the first dose in patients with COPD: the GLOW3 trial. Int J Chron Obstruct Pulmon Dis. 2012;7:503-13. doi: 10.2147/COPD.S32451. Epub 2012 Jul 31.

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