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Trial record **1 of 1** for: CNVA237A2314

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# Efficacy, Safety, and Tolerability of NVA237 Compared to Tiotropium in Patients With Chronic Obstructive Pulmonary Disease (COPD) (GLOW5)

**This study has been completed.**

**Sponsor:**
Novartis Pharmaceuticals

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

**ClinicalTrials.gov Identifier:**
NCT01613326

First received: February 17, 2012
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History of Changes

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

Results First Received: January 10, 2014

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Efficacy Study;<br>Intervention Model: Parallel Assignment;<br>Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor);<br>Primary Purpose: Treatment |
| **Condition:** | Chronic Obstructive Pulmonary Disease |
| | Drug: NVA237<br>Drug: Tiotropium |

| | |
|---|---|
| **Interventions:** | Drug: Placebo to tiotropium<br>Drug: Placebo to NVA237<br>Drug: salbutamol/albuterol |

## 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** |
|---|
| A total of 980 patients were screened, and 657 were randomized (327 to NVA237 and 330 to tiotropium). |

### Pre-Assignment Details

| **Significant events and approaches for the overall study following participant enrollment, but prior to group assignment** |
|---|
| Patients meeting the eligibility criteria were randomized to receive NVA237 50 µg o.d. or tiotropium 18 µg o.d. in a 1:1 ratio. Patients were stratified according to their smoking status (current / ex-smoker). |

### Reporting Groups

| | **Description** |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

### Participant Flow: Overall Study

| | **NVA237** | **Tiotropium** |
|---|---|---|
| **STARTED** | **327** | **330** |
| **COMPLETED** | **314** | **316** |
| **NOT COMPLETED** | | |

| | 13 | 14 |
|---|---|---|
| **Adverse Event** | **7** | **5** |
| **Withdrawal by Subject** | **3** | **4** |
| **Abnormal test procedure result(s)** | **2** | **0** |
| **inability to use device** | **1** | **0** |
| **Lack of Efficacy** | **0** | **1** |
| **Lost to Follow-up** | **0** | **1** |
| **Administrative** | **0** | **2** |
| **Protocol Violation** | **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** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | NVA237 | Tiotropium | Total |
|---|---|---|---|
| **Number of Participants [units: participants]** | **327** | **330** | **657** |
| **Age [units: Years] Mean (Standard Deviation)** | **63.2 (7.98)** | **63.7 (8.02)** | **63.5 (8.00)** |
| **Gender [units: participants]** | | | |
| **Female** | **90** | **82** | **172** |
| **Male** | **237** | **248** | **485** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment (Non-inferiority Analysis) [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment (Non-inferiority Analysis) |
| **Measure Description** | Forced Expiratory Volume in 1 second (FEV1) is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation, measured through spirometry testing. The trough in FEV1 was defined as the mean of two measurements at 23hours 15min and 23 hours 45min post dosing. ANCOVA model: Trough FEV1 = treatment + baseline FEV1 + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center (region). This analysis excluded values within 6 hours of rescue medication use or 7 days of systemic corticosteroid use. |
| **Time Frame** | Week 12 |

| | |
|---|---|
| **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.** |
| The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations or who did not take study drug as per protocol in the 14 day period prior to trough. |

**Reporting Groups**

| | Description |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **295** | **289** |
| **Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment (Non-inferiority Analysis) [units: Liters] Least Squares Mean (Standard Error)** | **1.405 (0.0173)** | **1.405 (0.0170)** |

**No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment (Non-inferiority Analysis)**

2. Secondary: Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment (Analysis of Superiority) [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment (Analysis of Superiority) |
| **Measure Description** | FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation, measured through spirometry testing. The trough in FEV1 was defined as the mean of two measurements at 23h 15min and 23h 45min post dosing. ANCOVA model: Trough FEV1 = treatment + baseline FEV1 + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center(region). This analysis excluded values within 6 hours of rescue medication use or 7 days of systemic corticosteroid. |
| **Time Frame** | Week 12 |
| **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.** |
|---|
| The Full Analysis Set (FAS) includes all randomized patients who received at least one dose of study drug and had available data for analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | **NVA237** | **Tiotropium** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **316** | **319** |
| **Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment (Analysis of** | | |

| | | |
|---|---|---|
| **Superiority)<br>[units: Liters]<br>Least Squares Mean (Standard Error)** | **1.398 (0.0154)** | **1.393 (0.0149)** |

**No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment (Analysis of Superiority)**

3. Secondary: Transition Dyspnea Index (TDI) Focal Score After 4 Weeks and 12 Weeks of Treatment [ Time Frame: Weeks 4 and 12 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Transition Dyspnea Index (TDI) Focal Score After 4 Weeks and 12 Weeks of Treatment |
| **Measure Description** | Transition Dyspnea Index (TDI) captures changes from baseline. The TDI score is based on three domains with each domain scored from -3 (major deterioration) to +3 (major improvement), to give an overall score of -9 to +9, a negative score indicating a deterioration from baseline. A TDI focal score of 1 is considered to be a clinically significant improvement from baseline.<br>ANCOVA model: TDI focal score = treatment + Baseline dyspnea index (BDI) + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center(region). Center is included as a random effect nested within region. |
| **Time Frame** | Weeks 4 and 12 |
| **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.** |
|---|
| The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations. |

**Reporting Groups**

| | **Description** |
|---|---|

| | |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **290** | **287** |
| **Transition Dyspnea Index (TDI) Focal Score After 4 Weeks and 12 Weeks of Treatment [units: Units on a scale] Least Squares Mean (Standard Error)** | | |
| **Week 4 (n= 289, 287)** | **2.209 (0.2957)** | **2.086 (0.2945)** |
| **Week 12 (n= 290, 285)** | **1.990 (0.3169)** | **2.178 (0.3159)** |

**No statistical analysis provided for Transition Dyspnea Index (TDI) Focal Score After 4 Weeks and 12 Weeks of Treatment**

4. Secondary: St. George's Respiratory Questionnaire Total Score After 12 Weeks of Treatment [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | St. George's Respiratory Questionnaire Total Score After 12 Weeks of Treatment |
| **Measure Description** | St. George's Respiratory Questionnaire (SGRQ) is a health related quality of life questionnaire consisting of 51 items in three areas: symptoms (respiratory symptoms and severity), activity (activities that cause or are limited by breathlessness) and impacts (social functioning and psychological disturbances due to airway disease). The total score is 0 to 100 with a higher score indicating poorer health status. ANCOVA model: SGRQ total score = treatment + baseline SGRQ score + baseline ICS use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center (region). |
| **Time Frame** | Week 12 |

| | |
|---|---|
| **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.** |
| The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations. |

**Reporting Groups**

| | Description |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **290** | **285** |
| **St. George's Respiratory Questionnaire Total Score After 12 Weeks of Treatment [units: Units on a scale] Least Squares Mean (Standard Error)** | **39.42 (1.313)** | **38.77 (1.306)** |

**No statistical analysis provided for St. George's Respiratory Questionnaire Total Score After 12 Weeks of Treatment**

5. Secondary: Change From Baseline in Mean Daily Number of Puffs of Rescue Medication Used Over the 12 Week Treatment [ Time Frame: Baseline and Day 1 to Week 12 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in Mean Daily Number of Puffs of Rescue Medication Used Over the 12 Week Treatment |
| **Measure Description** | A day with no rescue medication use is defined from the diary data as any day where the patient recorded no rescue medicine use during the previous 12 hours.<br>Baseline mean daily, daytime and nighttime (combined) number of puffs is defined as the average of the respective number of puffs. Only patients with a value at both baseline and post-baseline visits were included. |
| **Time Frame** | Baseline and Day 1 to Week 12 |
| **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.** |
|---|
| The per-protocol set included all randomized patients who received at least one dose of study drug, with a value at both baseline and post-baseline visits were included. |

**Reporting Groups**

| | **Description** |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | **NVA237** | **Tiotropium** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **296** | **290** |
| **Change From Baseline in Mean Daily Number of Puffs of Rescue Medication Used Over the 12 Week Treatment** | | |

| **[units: puffs]<br>Mean (Standard Deviation)** | | |
|---|---|---|
| **Baseline** | **4.09 (3.816)** | **4.10 (3.791)** |
| **Day 1 to week 12** | **2.76 (2.768)** | **2.84 (2.934)** |

**No statistical analysis provided for Change From Baseline in Mean Daily Number of Puffs of Rescue Medication Used Over the 12 Week Treatment**

6. Secondary: Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 1 and Week 4 [ Time Frame: Day 1 and Week 4 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 1 and Week 4 |
| **Measure Description** | FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation, measured through spirometry testing.<br>Trough FEV1 is defined as the average of the post-dose 23 h 15 min and the 23 h 45 min FEV1 values. Trough assessments taken outside 22 h 45 min - 24 h 15 min are excluded from this analysis.<br>ANCOVA model: Trough FEV1 = treatment + baseline FEV1 + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center(region). Center is included as a random effect nested within region. |
| **Time Frame** | Day 1 and Week 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.** |
|---|
| The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations or who did not take study drug as per protocol in the 14 day period prior to trough. |

**Reporting Groups**

| | Description |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **296** | **288** |
| **Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 1 and Week 4 [units: Liters] Least Squares Mean (Standard Error)** | | |
| **Day 1 (n=296, 288)** | **1.385 (0.0124)** | **1.386 (0.0122)** |
| **Week 4 (n=284, 280)** | **1.416 (0.0163)** | **1.416 (0.0160)** |

**No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 1 and Week 4**

7. Secondary: Peak Forced Expiratory Volume in 1 Second (FEV1) During 5 Min to 4 Hours Post-dose, at Day 1 and Week 12 [ Time Frame: 5 min to 4 hours post-dose at Day 1 and Week 12 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Peak Forced Expiratory Volume in 1 Second (FEV1) During 5 Min to 4 Hours Post-dose, at Day 1 and Week 12 |
| **Measure Description** | Spirometry was conducted according to internationally accepted standards. Peak FEV1 is the maximum FEV1 recorded during first 4 hours post dose. ANCOVA model: Peak FEV1 = treatment + baseline FEV1 + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center |

| | |
|---|---|
| | (region). Center is included as a random effect nested within region. This analysis excludes values within 6 hours of rescue medication use or 7 days of systemic corticosteroid use. |
| **Time Frame** | 5 min to 4 hours post-dose at Day 1 and Week 12 |
| **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.** |
|---|
| The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations |

**Reporting Groups**

| | **Description** |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | **NVA237** | **Tiotropium** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **298** | **292** |
| **Peak Forced Expiratory Volume in 1 Second (FEV1) During 5 Min to 4 Hours Post-dose, at Day 1 and Week 12 [units: Liters] Least Squares Mean (Standard Error)** | | |
| **Day 1 (n= 298, 292)** | **1.575 (0.0123)** | **1.520 (0.0121)** |
| **Week 12 (n= 290, 282)** | **1.577 (0.0166)** | **1.553 (0.0163)** |

**No statistical analysis provided for Peak Forced Expiratory Volume in 1 Second (FEV1) During 5 Min to 4 Hours Post-dose, at Day 1 and Week 12**

8. Secondary: Inspiratory Capacity (IC) at Each Time-point, by Visit [ Time Frame: (25 min, 1 h 55 min, 3 h 55 min, 23 h 40 min Day 1), (-20 min, 25 min, 23 h 40 min Week 4),(-20 min, 25 min, 1 h 55 min, 3 h 55 min, 23 h 40 min Week 12) ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Inspiratory Capacity (IC) at Each Time-point, by Visit |
| **Measure Description** | IC was measured with spirometry conducted according to internationally accepted standards. ANCOVA model: IC = treatment + baseline IC + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center(region). Center is included as a random effect nested within region. |
| **Time Frame** | (25 min, 1 h 55 min, 3 h 55 min, 23 h 40 min Day 1), (-20 min, 25 min, 23 h 40 min Week 4),(-20 min, 25 min, 1 h 55 min, 3 h 55 min, 23 h 40 min Week 12) |
| **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.** |
|---|
| The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations |

**Reporting Groups**

| | **Description** |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **216** | **214** |
| **Inspiratory Capacity (IC) at Each Time-point, by Visit [units: Liters] Least Squares Mean (Standard Error)** | | |
| **Day 1, 25 min (n= 216, 214)** | **2.378 (0.0263)** | **2.300 (0.0253)** |
| **Day 1, 1 h 55 min (n= 212, 208)** | **2.433 (0.0313)** | **2.335 (0.0298)** |
| **Day 1, 3 h 55 min (n= 211, 207)** | **2.343 (0.0325)** | **2.309 (0.0317)** |
| **Day 1, 23 h 40 min (n= 213, 212)** | **2.247 (0.0306)** | **2.244 (0.0294)** |
| **Week 4, -20 min (n= 204, 204)** | **2.231 (0.0342)** | **2.240 (0.0326)** |
| **Week 4, 25 min (n= 201, 200)** | **2.335 (0.0330)** | **2.334 (0.0312)** |
| **Week 4, 23 h 40 min (n=199,205)** | **2.284 (0.0362)** | **2.289 (0.0347)** |
| **Week 12, -20 min (n= 205, 204)** | **2.198 (0.0408)** | **2.227 (0.0394)** |
| **Week 12, 25 min (n= 215, 205)** | **2.292 (0.0397)** | **2.280 (0.0385)** |
| **Week 12, 1 h 55 min (n= 213, 203)** | **2.344 (0.0432)** | **2.289 (0.0421)** |
| **Week 12, 3 h 55 min (n= 203, 207)** | **2.313 (0.0395)** | **2.275 (0.0374)** |
| **Week 12, 23 h 40 min (n= 208, 206)** | **2.228 (0.0390)** | **2.262 (0.0373)** |

**No statistical analysis provided for Inspiratory Capacity (IC) at Each Time-point, by Visit**

9. Secondary: Forced Expiratory Volume in 1 Second (FEV1) at Each Time-point by Visit [ Time Frame: (5,15,30 min, 1, 2,3,4 h, 23h 15 min and 23h 45 min postdose of Day 1), (-45, -15 min predose, 5,15,30 min, 1h, 23h 15 min and 23h 45 min postdose of Week 4), (-45, -15 min predose, 5,15,30 min, 1, 2, 3,4 h, 23h 15 min and 23h 45 min postdose of Week 12) ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Forced Expiratory Volume in 1 Second (FEV1) at Each Time-point by Visit |
| **Measure Description** | Forced Expiratory Volume in 1 second (FEV1) is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation. FEV1 was analyzed using Analysis of Covariance (ANCOVA) model: FEV1 = treatment + baseline FEV1 + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center(region). Center is included as a random effect nested within region. |
| **Time Frame** | (5,15,30 min, 1, 2,3,4 h, 23h 15 min and 23h 45 min postdose of Day 1), (-45, -15 min predose, 5,15,30 min, 1h, 23h 15 min and 23h 45 min postdose of Week 4), (-45, -15 min predose, 5,15,30 min, 1, 2, 3,4 h, 23h 15 min and 23h 45 min postdose of Week 12) |
| **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.** |
|---|
| The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations |

**Reporting Groups**

| | **Description** |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | **NVA237** | **Tiotropium** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **291** | **286** |

| **Forced Expiratory Volume in 1 Second (FEV1) at Each Time-point by Visit [units: Liters] Least Squares Mean (Standard Error)** | | |
|---|---|---|
| **Day 1, 5 min (n= 283, 278)** | **1.382 (0.0087)** | **1.331 (0.0086)** |
| **Day 1, 15 min (n= 282, 276)** | **1.428 (0.0086)** | **1.365 (0.0084)** |
| **Day 1, 30 min (n= 285, 281)** | **1.442 (0.0104)** | **1.379 (0.0102)** |
| **Day 1, 1 hour (n= 291, 286)** | **1.482 (0.0111)** | **1.419 (0.0109)** |
| **Day 1, 2 hours (n= 290, 286)** | **1.517 (0.0127)** | **1.454 (0.0126)** |
| **Day 1, 3 hours (n= 291, 285)** | **1.527 (0.0141)** | **1.471 (0.0138)** |
| **Day 1, 4 hours (n= 285, 281)** | **1.490 (0.0137)** | **1.448 (0.0135)** |
| **Day 1, 23 h 15 min (n= 289, 279)** | **1.384 (0.0127)** | **1.384 (0.0124)** |
| **Day 1, 23 h 45 min (n= 285, 278)** | **1.381 (0.0139)** | **1.379 (0.0140)** |
| **Week 4, -45 min (n= 280, 280)** | **1.403 (0.0145)** | **1.391 (0.0140)** |
| **Week 4, -15 min (n= 278, 279)** | **1.388 (0.0146)** | **1.393 (0.0139)** |
| **Week 4, 5 min (n= 277, 274)** | **1.422 (0.0165)** | **1.423 (0.0160)** |
| **Week 4, 15 min (n= 271, 270)** | **1.459 (0.0163)** | **1.466 (0.0159)** |
| **Week 4, 30 min (n= 272, 276)** | **1.454 (0.0179)** | **1.442 (0.0175)** |
| **Week 4, 1 hr (n= 280, 282)** | **1.513 (0.0152)** | **1.494 (0.0147)** |
| **Week 4, 23 h 15 min (n= 278, 276)** | **1.422 (0.0171)** | **1.417 (0.0167)** |
| **Week 4, 23 h 45 min (n= 274, 276)** | **1.418 (0.0165)** | **1.416 (0.0162)** |
| **Week 12, -45 min (n= 286, 279)** | **1.394 (0.0176)** | **1.380 (0.0174)** |
| **Week 12, -15 min (n= 283, 279)** | **1.377 (0.0168)** | **1.370 (0.0165)** |
| **Week 12, 5 min (n= 283, 271)** | **1.430 (0.0182)** | **1.411 (0.0181)** |
| **Week 12, 15 min (n= 275, 271)** | **1.440 (0.0168)** | **1.423 (0.0163)** |

| | | |
|---|---|---|
| **Week 12, 30 min (n= 282, 278)** | **1.461 (0.0168)** | **1.432 (0.0163)** |
| **Week 12, 1 hr (n= 286, 279)** | **1.500 (0.0164)** | **1.475 (0.0160)** |
| **Week 12, 2 hours (n= 278, 277)** | **1.507 (0.0173)** | **1.484 (0.0169)** |
| **Week 12, 3 hours (n= 281, 279)** | **1.506 (0.0179)** | **1.484 (0.0175)** |
| **Week 12, 4 hours (n= 282, 280)** | **1.473 (0.0187)** | **1.462 (0.0183)** |
| **Week 12, 23 h 15 min (n= 276, 266)** | **1.414 (0.0185)** | **1.422 (0.0183)** |
| **Week 12, 23 h 45 min (n= 278, 276)** | **1.415 (0.0183)** | **1.420 (0.0180)** |

**No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) at Each Time-point by Visit**

10. Secondary: Forced Vital Capacity (FVC) at Each Time-point by Visit [ Time Frame: (5,15,30 min, 1, 2,3,4 h, 23h 15 min and 23h 45 min postdose of Day 1), (-45, -15 min predose, 5,15,30 min, 1h, 23h 15 min and 23h 45 min postdose of Week 4), (-45, -15 min predose, 5,15,30 min, 1, 2, 3,4 h, 23h 15 min and 23h 45 min postdose of Week 12) ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Forced Vital Capacity (FVC) at Each Time-point by Visit |
| **Measure Description** | Forced Vital Capacity (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. ANCOVA model: FVC = treatment + baseline FVC + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center(region). Center is included as a random effect nested within region. |
| **Time Frame** | (5,15,30 min, 1, 2,3,4 h, 23h 15 min and 23h 45 min postdose of Day 1), (-45, -15 min predose, 5,15,30 min, 1h, 23h 15 min and 23h 45 min postdose of Week 4), (-45, -15 min predose, 5,15,30 min, 1, 2, 3,4 h, 23h 15 min and 23h 45 min postdose of Week 12) |
| **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.**

The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations

**Reporting Groups**

| | Description |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **291** | **286** |
| **Forced Vital Capacity (FVC) at Each Time-point by Visit [units: Liters] Least Squares Mean (Standard Error)** | | |
| **Day 1, 5 min (n= 283, 278)** | **2.925 (0.0249)** | **2.874 (0.0247)** |
| **Day 1, 15 min (n= 282, 276)** | **3.004 (0.0281)** | **2.954 (0.0280)** |
| **Day 1, 30 min (n= 285, 281)** | **3.036 (0.0277)** | **2.991 (0.0274)** |
| **Day 1, 1 hour (n= 291, 286)** | **3.036 (0.0298)** | **3.006 (0.0296)** |
| **Day 1, 2 hours (n= 290, 286)** | **3.061 (0.0314)** | **3.029 (0.0312)** |
| **Day 1, 3 hours (n= 291, 285)** | **3.135 (0.0334)** | **3.111 (0.0329)** |
| **Day 1, 4 hours (n= 285, 281)** | **3.073 (0.0305)** | **3.046 (0.0301)** |
| **Day 1, 23 h 15 min (n= 289, 279)** | **2.911 (0.0287)** | **2.951 (0.0284)** |
| **Day 1, 23 h 45 min (n= 285, 278)** | **2.942 (0.0279)** | **2.951 (0.0279)** |

| | | |
|---|---|---|
| **Week 4, -45 min (n= 280, 280)** | **2.933 (0.0338)** | **2.943 (0.0331)** |
| **Week 4, -15 min (n= 278, 279)** | **2.879 (0.0356)** | **2.898 (0.0345)** |
| **Week 4, 5 min (n= 277, 274)** | **2.954 (0.0363)** | **2.997 (0.0354)** |
| **Week 4, 15 min (n= 271, 270)** | **3.021 (0.0378)** | **3.058 (0.0372)** |
| **Week 4, 30 min (n= 272, 276)** | **3.005 (0.0413)** | **3.011 (0.0407)** |
| **Week 4, 1 hr (n= 280, 282)** | **3.068 (0.0381)** | **3.093 (0.0374)** |
| **Week 4, 23 h 15 min (n= 278, 276)** | **2.982 (0.0364)** | **3.013 (0.0359)** |
| **Week 4, 23 h 45 min (n= 274, 276)** | **2.953 (0.0372)** | **2.978 (0.0366)** |
| **Week 12, -45 min (n= 286, 279)** | **2.889 (0.0416)** | **2.905 (0.0415)** |
| **Week 12, -15 min (n= 283, 279)** | **2.827 (0.0358)** | **2.837 (0.0355)** |
| **Week 12, 5 min (n= 283, 271)** | **2.929 (0.0403)** | **2.953 (0.0403)** |
| **Week 12, 15 min (n= 275, 271)** | **2.945 (0.0370)** | **2.963 (0.0364)** |
| **Week 12, 30 min (n= 282, 278)** | **2.963 (0.0374)** | **2.982 (0.0367)** |
| **Week 12, 1 hr (n= 286, 279)** | **3.011 (0.0377)** | **3.009 (0.0373)** |
| **Week 12, 2 hours (n= 278, 277)** | **3.008 (0.0390)** | **3.012 (0.0386)** |
| **Week 12, 3 hours (n= 281, 279)** | **3.014 (0.0404)** | **3.018 (0.0399)** |
| **Week 12, 4 hours (n= 282, 280)** | **2.964 (0.0404)** | **2.977 (0.0398)** |
| **Week 12, 23 h 15 min (n= 276, 266)** | **2.923 (0.0403)** | **2.953 (0.0404)** |
| **Week 12, 23 h 45 min (n= 278, 276)** | **2.929 (0.0436)** | **2.955 (0.0434)** |

**No statistical analysis provided for Forced Vital Capacity (FVC) at Each Time-point by Visit**

11. Secondary: Standardized Forced Expiratory Volume in One Second (FEV1) Area Under the Curve (AUC) (5 Min-4 h) Post-dose [ Time

Frame: Day 1 and week 12 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Standardized Forced Expiratory Volume in One Second (FEV1) Area Under the Curve (AUC) (5 Min-4 h) Post-dose |
| **Measure Description** | Forced Expiratory Volume in one second (FEV1) was measured with spirometry conducted according to internationally accepted standards.<br>Area Under the Curve (AUC) is calculated using the trapezoidal rule using the existing FEV1 measurements (i.e., the missing FEV1 measurements are not interpolated).<br>ANCOVA model: FEV1 AUC = treatment + baseline FEV1 + baseline Inhaled corticosteroid (ICS) use (Yes/No) + FEV1 reversibility components + baseline smoking status + region + center(region). Center is included as a random effect nested within region. |
| **Time Frame** | Day 1 and week 12 |
| **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.** |
|---|
| The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations. |

**Reporting Groups**

| | **Description** |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **298** | **292** |
| **Standardized Forced Expiratory Volume in One Second (FEV1) Area Under the Curve (AUC) (5 Min-4 h) Post-dose [units: Liters] Least Squares Mean (Standard Error)** | | |
| **Day 1 (n=298, 292)** | **1.496 (0.0109)** | **1.438 (0.0107)** |
| **Week 12 (290, 282)** | **1.493 (0.0164)** | **1.470 (0.0160)** |

**No statistical analysis provided for Standardized Forced Expiratory Volume in One Second (FEV1) Area Under the Curve (AUC) (5 Min-4 h) Post-dose**

12. Secondary: Event Free Rate at Weeks 4, 8 and 12 After Treatment [ Time Frame: Weeks 4, 8 and 12 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Event Free Rate at Weeks 4, 8 and 12 After Treatment |
| **Measure Description** | Event free rate was calculated as a percentage of participants who did not experience any moderate or severe COPD exacerbation leading to hospitalization/treatment with systemic corticosteroids/treatment with antibiotics. The event free rate reflects the percent of patients who did NOT have an exacerbation by 4, 8 and 12 weeks. Event-free rates are calculated at the end of the specified weeks (i.e. Day 29, Day 57 and Day 85) by the Kaplan Meier method. |
| **Time Frame** | Weeks 4, 8 and 12 |
| **Safety Issue** | Yes |

**Population Description**

**Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or**

**another method. Also provides relevant details such as imputation technique, as appropriate.**

The per-protocol set included all randomized patients who received at least one dose of study drug, with available data and without any major protocol deviations and described as patients with moderate to severe exacerbations were included in this analysis.

**Reporting Groups**

| | Description |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **29** | **22** |
| **Event Free Rate at Weeks 4, 8 and 12 After Treatment [units: percentage of participants] Number (95% Confidence Interval)** | | |
| **Week 4** | **95.6 (92.6 to 97.4)** | **96.6 (93.7 to 98.1)** |
| **Week 8** | **92.9 (89.3 to 95.3)** | **93.8 (90.4 to 96.1)** |
| **Week 12** | **90.2 (86.1 to 93.2)** | **92.4 (88.8 to 95.0)** |

**No statistical analysis provided for Event Free Rate at Weeks 4, 8 and 12 After Treatment**

13. Secondary: Mean Daily, Daytime and Nighttime (Combined) Symptom Scores Over the 12 Week Treatment Period [ Time Frame: 12

weeks ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Mean Daily, Daytime and Nighttime (Combined) Symptom Scores Over the 12 Week Treatment Period |
| **Measure Description** | Participants completed eDiaries providing scores 0 to 3 for symptoms: Cough and wheeze (none, mild, moderate, severe); sputum volume (none, less than 5 mL, 5-25 mL, >25 mL); sputum color (none, white-grey, yellow, green); lowest level of activity causing breathlessness (never or only when running, when walking uphill or upstairs, when walking on flat ground, at rest). Symptoms in the morning, for the previous night (no waking due to symptoms, woke up once due to symptoms, woke up more than once due to symptoms, woke up frequently or could not sleep due to symptoms). Symptoms experienced during the day that had prevented them for performing normal activities (not at all, a little, quite a lot, completely). The mean change from baseline in the total scores and in the individual scores was summarized by treatment. Only participants with a value at both baseline and post-baseline were included. Possible total scores 0-18 (night); 0-36 (day). A higher score means worsening of symptoms. |
| **Time Frame** | 12 weeks |
| **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.** |
|---|
| The per-protocol set included all randomized patients who received at least one dose of study drug. Only patients with a value at both baseline and post-baseline are included. |

**Reporting Groups**

| | **Description** |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

**Measured Values**

| | NVA237 | Tiotropium |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **296** | **290** |
| **Mean Daily, Daytime and Nighttime (Combined) Symptom Scores Over the 12 Week Treatment Period [units: units on a scale] Mean (Standard Deviation)** | | |
| **Baseline** | **7.21 (2.539)** | **6.90 (2.627)** |
| **Day 1 to Week 12** | **5.96 (2.469)** | **5.96 (2.531)** |

**No statistical analysis provided for Mean Daily, Daytime and Nighttime (Combined) Symptom Scores Over the 12 Week Treatment Period**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | No text entered. |
| **Additional Description** | No text entered. |

### Reporting Groups

| | Description |
|---|---|
| **NVA237** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

### Serious Adverse Events

| | NVA237 | Tiotropium |
|---|---|---|
| | | |

| | | |
|---|---|---|
| **Total, serious adverse events** | | |
| **# participants affected / at risk** | **11/327 (3.36%)** | **13/330 (3.94%)** |
| **Cardiac disorders** | | |
| **Cardiac failure † [1]** | | |
| **# participants affected / at risk** | **1/327 (0.31%)** | **0/330 (0.00%)** |
| **Gastrointestinal disorders** | | |
| **Diverticulum intestinal † [1]** | | |
| **# participants affected / at risk** | **1/327 (0.31%)** | **0/330 (0.00%)** |
| **Intestinal obstruction † [1]** | | |
| **# participants affected / at risk** | **0/327 (0.00%)** | **1/330 (0.30%)** |
| **Oesophagitis † [1]** | | |
| **# participants affected / at risk** | **0/327 (0.00%)** | **1/330 (0.30%)** |
| **Pancreatitis chronic † [1]** | | |
| **# participants affected / at risk** | **0/327 (0.00%)** | **1/330 (0.30%)** |
| **General disorders** | | |
| **Non-cardiac chest pain † [1]** | | |
| **# participants affected / at risk** | **1/327 (0.31%)** | **0/330 (0.00%)** |
| **Infections and infestations** | | |
| **Bronchitis † [1]** | | |
| **# participants affected / at risk** | **0/327 (0.00%)** | **1/330 (0.30%)** |
| **Cellulitis † [1]** | | |
| **# participants affected / at risk** | **1/327 (0.31%)** | **0/330 (0.00%)** |
| **Lobar pneumonia † [1]** | | |
| **# participants affected / at risk** | **1/327 (0.31%)** | **0/330 (0.00%)** |
| **Pneumonia † [1]** | | |

| | | |
|---|---|---|
| # participants affected / at risk | 2/327 (0.61%) | 2/330 (0.61%) |
| **Injury, poisoning and procedural complications** | | |
| Femur fracture † [1] | | |
| # participants affected / at risk | 1/327 (0.31%) | 0/330 (0.00%) |
| Spinal cord injury cervical † [1] | | |
| # participants affected / at risk | 1/327 (0.31%) | 0/330 (0.00%) |
| **Musculoskeletal and connective tissue disorders** | | |
| Myalgia † [1] | | |
| # participants affected / at risk | 0/327 (0.00%) | 1/330 (0.30%) |
| Spinal osteoarthritis † [1] | | |
| # participants affected / at risk | 1/327 (0.31%) | 0/330 (0.00%) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | | |
| Gastric cancer † [1] | | |
| # participants affected / at risk | 0/327 (0.00%) | 1/330 (0.30%) |
| **Nervous system disorders** | | |
| Dizziness † [1] | | |
| # participants affected / at risk | 1/327 (0.31%) | 0/330 (0.00%) |
| Hemiparesis † [1] | | |
| # participants affected / at risk | 0/327 (0.00%) | 1/330 (0.30%) |
| Ischaemic stroke † [1] | | |
| # participants affected / at risk | 0/327 (0.00%) | 2/330 (0.61%) |
| **Respiratory, thoracic and mediastinal disorders** | | |
| Acute respiratory failure † [1] | | |
| # participants affected / at risk | 0/327 (0.00%) | 1/330 (0.30%) |

| | | |
|---|---|---|
| **Chronic obstructive pulmonary disease † 1** | | |
| **# participants affected / at risk** | **3/327 (0.92%)** | **6/330 (1.82%)** |
| **Pulmonary arterial hypertension † 1** | | |
| **# participants affected / at risk** | **0/327 (0.00%)** | **1/330 (0.30%)** |

† 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** | NVA237 50 µg once a day and placebo to tiotropium once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |
| **Tiotropium** | Tiotropium 18 µg once a day and placebo to NVA237 once a day during 85 days. Salbutamol/albuterol was provided as rescue medication. |

### Other Adverse Events

| | **NVA237** | **Tiotropium** |
|---|---|---|
| **Total, other (not including serious) adverse events** | | |

| | | |
|---|---|---|
| **# participants affected / at risk** | **48/327 (14.68%)** | **54/330 (16.36%)** |
| **Respiratory, thoracic and mediastinal disorders** | | |
| **Chronic obstructive pulmonary disease † 1** | | |
| **# participants affected / at risk** | **48/327 (14.68%)** | **54/330 (16.36%)** |

† 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:<br>☐ 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.<br>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 pooled data (i.e.,data from all sites) in clinical trial or disclosure of trial results in their entirety.

**Results Point of Contact:**

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 4 161 324 1111

**No publications provided by Novartis**

**Publications automatically indexed to this study:**

Chapman KR, Beeh KM, Beier J, Bateman ED, D'Urzo A, Nutbrown R, Henley M, Chen H, Overend T, D'Andrea P. A blinded evaluation of the efficacy and safety of glycopyrronium, a once-daily long-acting muscarinic antagonist, versus tiotropium, in patients with COPD: the GLOW5 study. BMC Pulm Med. 2014 Jan 17;14:4. doi: 10.1186/1471-2466-14-4.

| | |
|---|---|
| Responsible Party: | Novartis ( Novartis Pharmaceuticals ) |
| ClinicalTrials.gov Identifier: | NCT01613326 History of Changes |
| Other Study ID Numbers: | **CNVA237A2314**<br>2011-000960-93 ( EudraCT Number ) |
| Study First Received: | February 17, 2012 |
| Results First Received: | January 10, 2014 |
| Last Updated: | April 22, 2014 |
| Health Authority: | United States: Food and Drug Administration<br>Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica<br>Canada: Health Canada<br>Croatia: Agency for Medicinal Product and Medical Devices<br>Czech Republic: State Institute for Drug Control |

Guatemala: Ministry of Public Health and Social Assistance
Estonia: The State Agency of Medicine
France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)
Germany: Federal Institute for Drugs and Medical Devices
India: Ministry of Health
Korea: Food and Drug Administration
Latvia: State Agency of Medicines
Lithuania: State Medicine Control Agency - Ministry of Health
Philippines: Department of Health
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
South Africa: Department of Health
Taiwan : Food and Drug Administration
Turkey: Ministry of Health