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Trial record **1 of 1** for: CQVA149A2204

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# Efficacy and Safety of QVA149 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:**
NCT00570778

First received: December 10, 2007
Last updated: January 23, 2013
Last verified: January 2013
History of Changes

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

Results First Received: October 23, 2012

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study;<br>Intervention Model: Crossover Assignment;<br>Masking: Double Blind (Subject, Investigator, Outcomes Assessor);<br>Primary Purpose: Treatment |
| **Condition:** | Chronic Obstructive Pulmonary Disease (COPD) |
| **Interventions:** | Drug: indacaterol/glycopyrrolate<br>Drug: indacaterol<br>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 |
|---|
| This was 4 arm crossover study. There was a 7 day washout period between each treatment period. 154 patients were randomized, 153 participants received study drug. 5 patients were excluded from the Modified Intent-to-treat population (MITT). 4 patients for protocol violations and 1 patient was randomized but did not receive study drug. |

### Reporting Groups

| | Description |
|---|---|
| **A: Ind 300 µg- Ind 600 µg- Placebo- Ind/Glyc 300/50 µg** | Treatment Period 1: One indacaterol (Ind) 300 µg capsule and one placebo capsule inhaled once daily via a single dose dry powder inhaler (SDDPI) for 7 days.<br>Treatment Period 2: Two indacaterol 300 µg capsules inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 3: Two placebo capsules inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 4: One indacaterol/glycopyrrolate (Ind/Glyc) 300/50 µg and one placebo capsule inhaled once daily via a SDDPI for 7 days. |
| **B: Ind 600 µg- Placebo- Ind/Glyc 300/50 µg- Ind 300 µg** | Treatment Period 1: Two indacaterol 300 µg capsules inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 2: Two placebo capsules inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 3: One indacaterol/glycopyrrolate (Ind/Glyc) 300/50 µg and one placebo capsule inhaled once daily via a SDDPI for 7 days. |

| | |
|---|---|
| | Treatment Period 4: One indacaterol (Ind) 300 µg capsule and one placebo capsule inhaled once daily via a SDDPI for 7 days. |
| **C: Ind/Glyc 300/50 µg- Ind 300 µg- Ind 600 µg- Placebo** | Treatment Period 1: One indacaterol/glycopyrrolate (Ind/Glyc) 300/50 µg and one placebo capsule inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 2: One indacaterol (Ind) 300 µg capsule and one placebo capsule inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 3: Two indacaterol 300 µg capsules inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 4: Two placebo capsules inhaled once daily via a SDDPI for 7 days. |
| **D: Placebo- Ind/Glyc 300/50 µg- Ind 300 µg- Ind 600 µg** | Treatment Period 1: Two placebo capsules inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 2: One indacaterol/glycopyrrolate (Ind/Glyc) 300/50 µg and one placebo capsule inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 3: One indacaterol (Ind) 300 µg capsule and one placebo capsule inhaled once daily via a SDDPI for 7 days.<br>Treatment Period 4: Two indacaterol 300 µg capsules inhaled once daily via a SDDPI for 7 days. |

### Participant Flow: Overall Study

| | A: Ind 300 µg- Ind 600 µg- Placebo- Ind/Glyc 300/50 µg | B: Ind 600 µg- Placebo- Ind/Glyc 300/50 µg- Ind 300 µg | C: Ind/Glyc 300/50 µg- Ind 300 µg- Ind 600 µg- Placebo | D: Placebo- Ind/Glyc 300/50 µg- Ind 300 µg- Ind 600 µg |
|---|---|---|---|---|
| **STARTED** | **41** | **38** | **37** | **38** |
| **Safety Population: Received Study Drug** | **41** [1] | **38** | **36** | **38** |
| **Modified Intent-to-treat Population** | **40** | **37** | **35** | **37** |

| | | | | |
|---|---|---|---|---|
| **COMPLETED** | **37** | **34** | **30** | **34** |
| **NOT COMPLETED** | **4** | **4** | **7** | **4** |
| **Protocol deviation** | **2** | **1** | **2** | **2** |
| **Adverse Event** | **0** | **1** | **4** | **1** |
| **Subject withdrew consent** | **0** | **1** | **0** | **1** |
| **Abnormal test procedure** | **1** | **0** | **0** | **0** |
| **Unsatisfactory therapeutic effect** | **1** | **0** | **0** | **0** |
| **Lost to Follow-up** | **0** | **0** | **1** | **0** |
| **Subject no longer requires study drug** | **0** | **1** | **0** | **0** |

[1] Safety Population included all participants who received at least 1 dose of any study drug.

## Baseline Characteristics

Hide Baseline Characteristics

### Population Description

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

### Reporting Groups

| | Description |
|---|---|
| **Overall Population** | Participants were randomized and received the following 4 treatments: 1-Two placebo capsules inhaled once daily via a SDDPI for 7 days, 2-One indacaterol/glycopyrrolate (Ind/Glyc) 300/50 µg and one placebo capsule inhaled once daily via a SDDPI for 7 days, 3-One Indacaterol (Ind) 300 µg capsule and one placebo capsule inhaled once daily via a SDDPI for 7 days and 4-Two Indacaterol 300 µg capsules inhaled once daily via a SDDPI for 7 days. There was a 7 day washout period between the four treatment periods. |

**Baseline Measures**

| | Overall Population |
|---|---|
| **Number of Participants [units: participants]** | **153** |
| **Age [1] [units: years] Mean (Standard Deviation)** | **61.7 (8.5)** |
| **Gender [units: participants]** | |
| **Female** | **59** |
| **Male** | **94** |

[1] Baseline characteristics are based on the Safety Population that consists of all participants who received study drug.

## Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 7 [ Time Frame: Baseline, Day 7 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 7 |
| | |

| | |
|---|---|
| **Measure Description** | Spirometry testing was performed in accordance with American Thoracic Society standards. Trough FEV1 was defined as the average of the 23 hour 15 minute and 23 hour 45 minute measurements post dosing. Baseline FEV1 is the mean of the 45 minute and 15 minute pre-dose FEV1 values at day 1 of each period. Least square means are based on the Analysis of Covariance Trough FEV1 at day 7 = sequence effect + patient(sequence) + period effect + treatment effect + (period) baseline FEV1 + error. |
| **Time Frame** | Baseline, Day 7 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Participants from the Modified Intent-to-treat population (includes all participants who received study drug) with data available for analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol/Glycopyrrolate 300/50 µg** | One indacaterol/glycopyrrolate 300/50 µg capsule + 1 placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Indacaterol 300 µg** | One capsule indacaterol 300 µg + one placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Indacaterol 600 µg** | Two indacaterol 300 µg capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Placebo** | Two placebo capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |

**Measured Values**

| | **Indacaterol/Glycopyrrolate 300/50 µg** | **Indacaterol 300 µg** | **Indacaterol 600 µg** | **Placebo** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **140** | **138** | **140** | **136** |
| **Change From Baseline in Trough Forced Expiratory Volume in 1** | | | | |

| | | | | |
|---|---|---|---|---|
| **Second (FEV1) at Day 7 [units: Liters] Least Squares Mean (Standard Error)** | **1.512 (0.0143)** | **1.389 (0.0144)** | **1.395 (0.0143)** | **1.286 (0.0145)** |

**No statistical analysis provided for Change From Baseline in Trough Forced Expiratory Volume in 1 Second (FEV1) at Day 7**

2. Secondary: Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under Curve (AUC) 5 Minutes-12 Hours at Day 7 [ Time Frame: Day 7 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under Curve (AUC) 5 Minutes-12 Hours at Day 7 |
| **Measure Description** | Spirometry testing was performed in accordance with American Thoracic Society standards. FEV1 was assessed at 5, 15, 30 minutes, 1, 2, 3, 4, 5, 6, 8, 10 and 12 hours post dose on Day 7. Standardized (with respect to time) AUC (5 minutes-12 hours) for FEV1 on day 7 was calculated using the trapezoidal rule. Least square means are based on the Analysis of Covariance: FEV1 AUC = sequence effect + patient (sequence) + period + treatment + baseline FEV1 (period) + error. |
| **Time Frame** | Day 7 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Participants from the Modified Intent-to-treat population (includes all participants who received study drug) with data available for analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol/Glycopyrrolate 300/50 µg** | One indacaterol/glycopyrrolate 300/50 µg capsule + 1 placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |

| | |
|---|---|
| **Indacaterol 300 µg** | One capsule indacaterol 300 µg + one placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Indacaterol 600 µg** | Two indacaterol 300 µg capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Placebo** | Two placebo capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |

**Measured Values**

| | **Indacaterol/Glycopyrrolate 300/50 µg** | **Indacaterol 300 µg** | **Indacaterol 600 µg** | **Placebo** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **142** | **140** | **142** | **140** |
| **Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under Curve (AUC) 5 Minutes-12 Hours at Day 7 [units: Liters] Least Squares Mean (Standard Error)** | **1.610 (0.0180)** | **1.473 (0.0181)** | **1.457 (0.0180)** | **1.317 (0.0185)** |

**No statistical analysis provided for Standardized Forced Expiratory Volume in 1 Second (FEV1) Area Under Curve (AUC) 5 Minutes-12 Hours at Day 7**

3. Secondary: Number of Participants With Adverse Events, Serious Adverse Events and Discontinuations Due to Adverse Events [ Time Frame: 47 days ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Number of Participants With Adverse Events, Serious Adverse Events and Discontinuations Due to Adverse Events |
| **Measure Description** | Additional information about adverse events can be found in the Adverse Event Section. |
| **Time Frame** | 47 days |
| **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.** |
|---|
| Safety population includes all participants who received at least 1 dose of study drug. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol/Glycopyrrolate 300/50 µg** | One indacaterol/glycopyrrolate 300/50 µg capsule + 1 placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Indacaterol 300 µg** | One capsule indacaterol 300 µg + one placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Indacaterol 600 µg** | Two indacaterol 300 µg capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Placebo** | Two placebo capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |

**Measured Values**

| | **Indacaterol/Glycopyrrolate 300/50 µg** | **Indacaterol 300 µg** | **Indacaterol 600 µg** | **Placebo** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **142** | **141** | **141** | **143** |
| **Number of Participants With Adverse Events, Serious Adverse Events and Discontinuations Due to Adverse Events [units: Participants]** | | | | |
| **Serious Adverse Events** | **2** | **0** | **0** | **0** |
| **Adverse Events** | **39** | **31** | **37** | **31** |
| **Discontinuations Due to Adverse Events** | **3** | **0** | **2** | **0** |

**No statistical analysis provided for Number of Participants With Adverse Events, Serious Adverse Events and Discontinuations Due to Adverse**

**Events**

## Serious Adverse Events

Hide Serious Adverse Events

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

### Reporting Groups

| | Description |
|---|---|
| **Indacaterol/Glycopyrrolate 300/50 µg** | One indacaterol/glycopyrrolate 300 µg /50 µg capsule + 1 placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Indacaterol 300 µg** | One capsule indacaterol 300 µg + one placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Indacaterol 600 µg** | Two indacaterol 300 µg capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Placebo** | Two placebo capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |

### Serious Adverse Events

| | Indacaterol/Glycopyrrolate 300/50 µg | Indacaterol 300 µg | Indacaterol 600 µg | Placebo |
|---|---|---|---|---|
| **Total, serious adverse events** | | | | |
| **# participants affected / at risk** | **2/142 (1.41%)** | **0/141 (0.00%)** | **0/141 (0.00%)** | **0/143 (0.00%)** |
| **Injury, poisoning and procedural complications** | | | | |

| | | | | |
|---|---|---|---|---|
| **Fall † 1** | | | | |
| **# participants affected / at risk** | **1/142 (0.70%)** | **0/141 (0.00%)** | **0/141 (0.00%)** | **0/143 (0.00%)** |
| **Humerus fracture † 1** | | | | |
| **# participants affected / at risk** | **1/142 (0.70%)** | **0/141 (0.00%)** | **0/141 (0.00%)** | **0/143 (0.00%)** |
| **Respiratory, thoracic and mediastinal disorders** | | | | |
| **Chronic obstructive pulmonary disease † 1** | | | | |
| **# participants affected / at risk** | **1/142 (0.70%)** | **0/141 (0.00%)** | **0/141 (0.00%)** | **0/143 (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** | 2% |

### Reporting Groups

| | **Description** |
|---|---|
| **Indacaterol/Glycopyrrolate 300/50 µg** | One indacaterol/glycopyrrolate 300 µg /50 µg capsule + 1 placebo capsule inhaled once daily via a |

| | |
|---|---|
| | single dose dry powder inhaler for 7 days. |
| **Indacaterol 300 µg** | One capsule indacaterol 300 µg + one placebo capsule inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Indacaterol 600 µg** | Two indacaterol 300 µg capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |
| **Placebo** | Two placebo capsules inhaled once daily via a single dose dry powder inhaler for 7 days. |

## Other Adverse Events

| | Indacaterol/Glycopyrrolate 300/50 µg | Indacaterol 300 µg | Indacaterol 600 µg | Placebo |
|---|---|---|---|---|
| **Total, other (not including serious) adverse events** | | | | |
| **# participants affected / at risk** | **12/142 (8.45%)** | **14/141 (9.93%)** | **15/141 (10.64%)** | **15/143 (10.49%)** |
| **Gastrointestinal disorders** | | | | |
| **Diarrhoea † [1]** | | | | |
| **# participants affected / at risk** | **0/142 (0.00%)** | **3/141 (2.13%)** | **2/141 (1.42%)** | **2/143 (1.40%)** |
| **Infections and infestations** | | | | |
| **Nasopharyngitis † [1]** | | | | |
| **# participants affected / at risk** | **1/142 (0.70%)** | **6/141 (4.26%)** | **2/141 (1.42%)** | **5/143 (3.50%)** |
| **Nervous system disorders** | | | | |
| **Headache † [1]** | | | | |
| **# participants affected / at risk** | **7/142 (4.93%)** | **2/141 (1.42%)** | **6/141 (4.26%)** | **2/143 (1.40%)** |
| **Respiratory, thoracic and mediastinal disorders** | | | | |
| **Cough † [1]** | | | | |
| **# participants affected / at risk** | **4/142 (2.82%)** | **1/141 (0.71%)** | **3/141 (2.13%)** | **2/143 (1.40%)** |

| | | | | |
|---|---|---|---|---|
| **Dyspnoea † 1** | | | | |
| **# participants affected / at risk** | **2/142 (1.41%)** | **2/141 (1.42%)** | **4/141 (2.84%)** | **4/143 (2.80%)** |

† 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.<br>Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. |

**Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

**Results Point of Contact:**

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

**No publications provided by Novartis**

**Publications automatically indexed to this study:**

van Noord JA, Buhl R, Laforce C, Martin C, Jones F, Dolker M, Overend T. QVA149 demonstrates superior bronchodilation compared with indacaterol or placebo in patients with chronic obstructive pulmonary disease. Thorax. 2010 Dec;65(12):1086-91. doi: 10.1136/thx.2010.139113. Epub 2010 Oct 26.

| | |
|---|---|
| Responsible Party: | Novartis ( Novartis Pharmaceuticals ) |
| ClinicalTrials.gov Identifier: | NCT00570778 History of Changes |
| Other Study ID Numbers: | **CQVA149A2204** |
| Study First Received: | December 10, 2007 |
| Results First Received: | October 23, 2012 |
| Last Updated: | January 23, 2013 |
| Health Authority: | United States: Food and Drug Administration<br>Belgium: Federal Agency for Medicinal Products and Health Products<br>Netherlands: Medicines Evaluation Board (MEB)<br>Germany: Federal Institute for Drugs and Medical Devices<br>Canada: Health Canada |