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Trial record **1 of 1** for: CQVA149A2305

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Effect of QVA149 on Exercise Tolerance in Patients With Chronic Obstructive Pulmonary Disease (COPD) (BRIGHT)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01294787

First received: February 10, 2011
Last updated: March 19, 2013
Last verified: March 2013
History of Changes

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Results First Received: November 29, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	COPD
Interventions:	Drug: indacaterol and glycopyrronium bromide (QVA149) Drug: placebo Drug: tiotropium

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
The study consisted of a maximum 28 day screening period, and three, 3-week treatment periods followed by a study completion evaluation. A washout of 21 days was used to separate the treatment periods.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
A total of 85 patients were randomized and 73 patients completed the study. Since this was a cross-over study a participant may be counted in more than 1 group: 77 participants were treated with QVA149, 83 participants treated with tiotropium and 77 participants treated with placebo. One randomized patient did not receive study drug.

Reporting Groups

	Description
QVA149 / Placebo / Tiotropium	Participants received three, 3-week treatment periods followed by a study completion evaluation. A washout of 21 days was used to separate the treatment periods.
QVA149 / Tiotropium / Placebo	Participants received three, 3-week treatment periods followed by a study completion evaluation. A washout of 21 days was used to separate the treatment periods.
Placebo / QVA149 / Tiotropium	Participants received three, 3-week treatment periods followed by a study completion evaluation. A washout of 21 days was used to separate the treatment periods.
Placebo / Tiotropium / QVA149	Participants received three, 3-week treatment periods followed by a study completion evaluation. A washout of 21 days was used to separate the treatment periods.
Tiotropium / QAV149 / Placebo	Participants received three, 3-week treatment periods followed by a study completion evaluation. A washout of 21 days was used to separate the treatment periods.
Tiotropium / Placebo / QVA149	Participants received three, 3-week treatment periods followed by a study completion evaluation. A washout of 21 days was used to separate the treatment periods.

Participant Flow for 3 periods

Period 1: Period 1

	QVA149 / Placebo / Tiotropium	QVA149 / Tiotropium / Placebo	Placebo / QVA149 / Tiotropium	Placebo / Tiotropium / QVA149	Tiotropium / QAV149 / Placebo	Tiotropium / Placebo / QVA149
STARTED	12	16	14	12	16	15 [1]
COMPLETED	12	16	13	11	14	13
NOT COMPLETED	0	0	1	1	2	2
Adverse Event	0	0	0	0	1	0
Withdrawal by Subject	0	0	0	1	1	1
Administrative problem	0	0	1	0	0	1

[1] One randomized participant did not receive study drug

Period 2: Period 2

	QVA149 / Placebo / Tiotropium	QVA149 / Tiotropium / Placebo	Placebo / QVA149 / Tiotropium	Placebo / Tiotropium / QVA149	Tiotropium / QAV149 / Placebo	Tiotropium / Placebo / QVA149
STARTED	12	16	13	11	14	13
COMPLETED	12	13	13	9	14	13
NOT COMPLETED	0	3	0	2	0	0
Adverse Event	0	3	0	1	0	0

No longer needs study drug	0	0	0	1	0	0

Period 3: Period 3

	QVA149 / Placebo / Tiotropium	QVA149 / Tiotropium / Placebo	Placebo / QVA149 / Tiotropium	Placebo / Tiotropium / QVA149	Tiotropium / QAV149 / Placebo	Tiotropium / Placebo / QVA149
STARTED	12	13	13	9	14	13
COMPLETED	12	13	13	9	13	13
NOT COMPLETED	0	0	0	0	1	0
Adverse Event	0	0	0	0	1	0

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
All Participants	Participants received three, 3-week treatment periods followed by a study completion evaluation. A washout of 21 days was used to separate the treatment periods. One participant was randomized but did not receive study drug.

Baseline Measures

	All Participants
Number of Participants [units: participants]	**84**
Age [units: years] Mean (Standard Deviation)	
All participants	**62.1 (8.11)**
Gender [units: participants]	
Female	**53**
Male	**31**

Outcome Measures

Hide All Outcome Measures

1. Primary: Exercise Tolerance Comparison Between QVA149 and Placebo Groups [Time Frame: 3 weeks]

Measure Type	Primary
Measure Title	Exercise Tolerance Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured by exercise endurance time (in seconds) during a sub-maximal constant load cycle ergometry test ((SMETT)which is a cycle exercise test) after three weeks of treatment.
Time Frame	3 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler

Measured Values

	QVA149	**Placebo**
Number of Participants Analyzed [units: participants]	**77**	**74**
Exercise Tolerance Comparison Between QVA149 and Placebo Groups [units: Seconds] Least Squares Mean (Standard Error)	**507.8 (19.30)**	**448.3 (19.49)**

No statistical analysis provided for Exercise Tolerance Comparison Between QVA149 and Placebo Groups

2. Secondary: Dynamic Inspiratory Capacity Comparison Between QVA149 and Placebo Groups [Time Frame: 3 weeks]

Measure Type	Secondary
Measure Title	Dynamic Inspiratory Capacity Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using dynamic

	inspiratory capacity at isotime during sub-maximal constant load cycle ergometry test ((SMETT)a cycle exercise test), after three weeks of treatment.
Time Frame	3 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler.

Measured Values

	QVA149	**Tiotropium**	**Placebo**
Number of Participants Analyzed [units: participants]	**65**	**67**	**59**
Dynamic Inspiratory Capacity Comparison Between QVA149 and Placebo Groups [units: Liters] Least Squares Mean (Standard Error)	**2.42 (0.034)**	**2.29 (0.033)**	**2.11 (0.035)**

No statistical analysis provided for Dynamic Inspiratory Capacity Comparison Between QVA149 and Placebo Groups

3. Secondary: Trough 24 Hour Post Dose Inspiratory Capacity Comparison Between QVA149 and Placebo Groups [Time Frame: 3 weeks]

Measure Type	Secondary
Measure Title	Trough 24 Hour Post Dose Inspiratory Capacity Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using trough 24 hour post dose inspiratory capacity after three weeks of treatment.
Time Frame	3 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler

Measured Values

	QVA149	Tiotropium	Placebo
Number of Participants Analyzed [units: participants]	**67**	**73**	**66**
Trough 24 Hour Post Dose Inspiratory Capacity Comparison Between QVA149 and Placebo			

Groups [units: Liters] Least Squares Mean (Standard Error)	**2.25 (0.035)**	**2.10 (0.034)**	**2.06 (0.035)**

No statistical analysis provided for Trough 24 Hour Post Dose Inspiratory Capacity Comparison Between QVA149 and Placebo Groups

4. Secondary: Trough 24 Hour Post Dose Forced Expiratory Volume in One Second Comparison Between QVA149 and Placebo Groups [Time Frame: 3 weeks]

Measure Type	Secondary
Measure Title	Trough 24 Hour Post Dose Forced Expiratory Volume in One Second Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using trough 24 hour post dose Forced Expiratory Volume in one second (FEV1) after three weeks of treatment.
Time Frame	3 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.

Placebo	Placebo, delivered once daily via single-dose dry powder inhaler

Measured Values

	QVA149	Tiotropium	Placebo
Number of Participants Analyzed [units: participants]	**76**	**78**	**73**
Trough 24 Hour Post Dose Forced Expiratory Volume in One Second Comparison Between QVA149 and Placebo Groups [units: Liters] Least Squares Mean (Standard Error)	**1.53 (0.020)**	**1.43 (0.020)**	**1.33 (0.021)**

No statistical analysis provided for Trough 24 Hour Post Dose Forced Expiratory Volume in One Second Comparison Between QVA149 and Placebo Groups

5. Secondary: Pulmonary Function Test Comparison Between QVA149 and Placebo Groups [Time Frame: day 1 and day 21]

Measure Type	Secondary
Measure Title	Pulmonary Function Test Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using the pulmonary function test for Slow Vital Capacity (SVC) on day 1 and day 21, at 5 min and 15 min post dose as determined by body plethysmography.
Time Frame	day 1 and 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.

Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler

Measured Values

	QVA149	Tiotropium	Placebo
Number of Participants Analyzed [units: participants]	**77**	**83**	**77**
Pulmonary Function Test Comparison Between QVA149 and Placebo Groups [units: Liters] Least Squares Mean (Standard Error)			
Day 1- 5 min post-dose	**3.37 (0.028)**	**3.22 (0.027)**	**3.14 (0.028)**
Day 1- 15 min post-dose	**3.43 (0.026)**	**3.32 (0.025)**	**3.16 (0.026)**
Day 21- 5 min post-dose	**3.37 (0.037)**	**3.26 (0.036)**	**3.08 (0.038)**
Day 21- 15 min post-dose	**3.38 (0.040)**	**3.29 (0.038)**	**3.09 (0.039)**

No statistical analysis provided for Pulmonary Function Test Comparison Between QVA149 and Placebo Groups

6. Secondary: Pulmonary Function Test (RV) Comparison Between QVA149 and Placebo Groups [Time Frame: day 1 and day 21]

Measure Type	Secondary

Measure Title	Pulmonary Function Test (RV) Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using the pulmonary function test for Residual Volume (RV) on day 1 and day 21, at 5 min and 15 min post dose as determined by body plethysmography.
Time Frame	day 1 and 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler

Measured Values

	QVA149	**Tiotropium**	**Placebo**
Number of Participants Analyzed [units: participants]	**77**	**83**	**77**
Pulmonary Function Test (RV) Comparison Between QVA149 and Placebo Groups [units: Liters] Least Squares Mean (Standard Error)			
Day 1 - 5 min post-dose	**3.66 (0.051)**	**3.89 (0.048)**	**3.94 (0.050)**

Day 1 - 15 min post-dose	**3.63 (0.048)**	**3.66 (0.046)**	**3.89 (0.048)**
Day 21- 5 min post-dose	**3.58 (0.063)**	**3.69 (0.061)**	**4.03 (0.064)**
Day 21- 15 min post-dose	**3.54 (0.066)**	**3.59 (0.062)**	**3.96 (0.065)**

No statistical analysis provided for Pulmonary Function Test (RV) Comparison Between QVA149 and Placebo Groups

7. Secondary: Pulmonary Function Test (SGaw) Comparison Between QVA149 and Placebo Groups [Time Frame: day 1 and day 21]

Measure Type	Secondary
Measure Title	Pulmonary Function Test (SGaw) Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using the pulmonary function test for Specific Airway Conductance (SGaw) on day 1 and day 21, at 5 min and 15 min post dose as determined by body plethysmography.
Time Frame	day 1 and 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.

Placebo	Placebo, delivered once daily via single-dose dry powder inhaler

Measured Values

	QVA149	Tiotropium	Placebo
Number of Participants Analyzed [units: participants]	**77**	**83**	**77**
Pulmonary Function Test (SGaw) Comparison Between QVA149 and Placebo Groups [units: Kilo Pascal per second] Least Squares Mean (Standard Error)			
Day 1- 5 min post-dose	**0.71 (0.035)**	**0.58 (0.033)**	**0.50 (0.035)**
Day 1- 15 min post-dose	**0.71 (0.064)**	**0.79 (0.061)**	**0.50 (0.063)**
Day 21- 5 min post-dose	**0.76 (0.041)**	**0.64 (0.039)**	**0.50 (0.041)**
Day 21- 15 min post-dose	**0.79 (0.039)**	**0.67 (0.038)**	**0.47 (0.038)**

No statistical analysis provided for Pulmonary Function Test (SGaw) Comparison Between QVA149 and Placebo Groups

8. Secondary: Pulmonary Function Test (FRC) Comparison Between QVA149 and Placebo Groups [Time Frame: day 1 and day 21]

Measure Type	Secondary
Measure Title	Pulmonary Function Test (FRC) Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using the pulmonary function test for Functional Residual Capacity (FRC) on day 1 and day 21, at 5 min and 15 min post dose as determined by body plethysmography.
Time Frame	day 1 and 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler

Measured Values

	QVA149	**Tiotropium**	**Placebo**
Number of Participants Analyzed [units: participants]	**77**	**83**	**77**
Pulmonary Function Test (FRC) Comparison Between QVA149 and Placebo Groups [units: Liters] Least Squares Mean (Standard Error)			
Day 1- 5 min post-dose	**4.68 (0.057)**	**4.78 (0.055)**	**4.98 (0.057)**
Day 1- 15 min post-dose	**4.62 (0.060)**	**4.63 (0.058)**	**4.92 (0.059)**
Day 21- 5 min post-dose	**4.58 (0.068)**	**4.66 (0.066)**	**5.00 (0.068)**
Day 21- 15 min post-dose	**4.53 (0.067)**	**4.55 (0.065)**	**4.91 (0.067)**

No statistical analysis provided for Pulmonary Function Test (FRC) Comparison Between QVA149 and Placebo Groups

9. Secondary: Spirometry After Three Weeks of Treatment on Patients Not Exercising [Time Frame: 3 weeks]

Measure Type	Secondary
Measure Title	Spirometry After Three Weeks of Treatment on Patients Not Exercising
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using dynamic inspiratory capacity post-dose pre-exercise after three weeks of treatment.
Time Frame	3 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
Indacaterol and Glycopyrronium Bromide (QVA149)	QVA149 delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler.

Measured Values

	Indacaterol and Glycopyrronium Bromide (QVA149)	**Tiotropium**	**Placebo**
Number of Participants Analyzed [units: participants]	**76**	**80**	**70**
Spirometry After Three Weeks of Treatment on Patients Not Exercising		**2.19**	**2.01**

[units: Liters] Least Squares Mean (Standard Error)	**2.34 (0.032)**	**(0.031)**	**(0.033)**

No statistical analysis provided for Spirometry After Three Weeks of Treatment on Patients Not Exercising

10. Secondary: Exertional Dyspnea Comparison Between QVA149 and Placebo Groups [Time Frame: 3 weeks]

Measure Type	Secondary
Measure Title	Exertional Dyspnea Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured using exertional dyspnea Borg CR10 Scale® (After 3 weeks of treatment, before, during and after exercise, patients were asked to rate the intensity of their breathing and leg discomfort using the Borg CR10 Scale®). This scale consists of 12-point score that the participants 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.
Time Frame	3 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.

Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler.

Measured Values

	QVA149	Tiotropium	Placebo
Number of Participants Analyzed [units: participants]	**66**	**70**	**61**
Exertional Dyspnea Comparison Between QVA149 and Placebo Groups [units: units on a scale] Least Squares Mean (Standard Error)	**3.77 (0.256)**	**3.59 (0.248)**	**3.87 (0.259)**

No statistical analysis provided for Exertional Dyspnea Comparison Between QVA149 and Placebo Groups

11. Secondary: Leg Discomfort During Exercise Comparison Between QVA149 and Placebo Groups [Time Frame: 3 weeks]

Measure Type	Secondary
Measure Title	Leg Discomfort During Exercise Comparison Between QVA149 and Placebo Groups
Measure Description	The effect of indacaterol and glycopyrronium bromide (QVA149) compared to placebo on leg discomfort was measured using Borg CR10 Scale® during sub-maximal constant load cycle ergometry test after three weeks treatment.
Time Frame	3 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data

available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler.

Measured Values

	QVA149	Tiotropium	Placebo
Number of Participants Analyzed [units: participants]	**66**	**70**	**61**
Leg Discomfort During Exercise Comparison Between QVA149 and Placebo Groups [units: units on a scale] Least Squares Mean (Standard Error)	**4.53 (0.243)**	**4.57 (0.234)**	**4.43 (0.245)**

No statistical analysis provided for Leg Discomfort During Exercise Comparison Between QVA149 and Placebo Groups

12. Secondary: Exercise Endurance Comparison Between QVA149 and Tiotropium Groups [Time Frame: 3 weeks]

Measure Type	Secondary
Measure Title	Exercise Endurance Comparison Between QVA149 and Tiotropium Groups
Measure Description	Effect of QVA149 110/50 µg o.d. compared with tiotropium 18 µg o.d. in patients with moderate to severe COPD with respect to exercise endurance was measured by a sub-maximal constant load cycle ergometry test ((SMETT)cycle exercise test) after three weeks of treatment.
Time Frame	3 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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
Indacaterol and Glycopyrronium Bromide (QVA149)	QVA149 delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.

Measured Values

	Indacaterol and Glycopyrronium Bromide (QVA149)	**Tiotropium**
Number of Participants Analyzed [units: participants]	**77**	**80**
Exercise Endurance Comparison Between QVA149 and Tiotropium Groups [units: Seconds] Least Squares Mean (Standard Error)	**507.8 (19.30)**	**514 (18.99)**

No statistical analysis provided for Exercise Endurance Comparison Between QVA149 and Tiotropium Groups

13. Secondary: Exercise Endurance Time Comparison After a Single Dose of QVA149 Versus Placebo [Time Frame: Day 1]

Measure Type	Secondary
Measure Title	Exercise Endurance Time Comparison After a Single Dose of QVA149 Versus Placebo

Measure Description	The effect of a single dose of indacaterol and glycopyrronium bromide (QVA149) compared to placebo was measured with respect to exercise endurance time during sub-maximal constant load cycle ergometry test ((SMETT)cycle exercise test).
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.
Participants from the Full Analysis Set, defined as all randomized participants who received at least one dose of study drug, with data available for analysis.

Reporting Groups

	Description
QVA149	Indacaterol and glycopyrronium bromide (QVA149) delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler

Measured Values

	QVA149	Tiotropium	Placebo
Number of Participants Analyzed [units: participants]	**77**	**83**	**77**
Exercise Endurance Time Comparison After a Single Dose of QVA149 Versus Placebo [units: Seconds] Least Squares Mean (Standard Error)	**492.8 (17.28)**	**481.0 (16.77)**	**468.8 (17.18)**

No statistical analysis provided for Exercise Endurance Time Comparison After a Single Dose of QVA149 Versus Placebo

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Indacaterol and Glycopyrronium Bromide (QVA149)	QVA149 delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler.

Serious Adverse Events

	Indacaterol and Glycopyrronium Bromide (QVA149)	Tiotropium	Placebo
Total, serious adverse events			
# participants affected / at risk	**1/77 (1.30%)**	**1/83 (1.20%)**	**1/77 (1.30%)**
Cardiac disorders			
Acute myocardial infarction † [1]			
# participants affected / at risk	**0/77 (0.00%)**	**1/83 (1.20%)**	**0/77 (0.00%)**
Gastrointestinal disorders			
Colitis † [1]			
# participants affected / at risk	**1/77 (1.30%)**	**0/83 (0.00%)**	**0/77 (0.00%)**
Infections and infestations			

Pneumonia † 1			
# participants affected / at risk	**0/77 (0.00%)**	**0/83 (0.00%)**	**1/77 (1.30%)**

† 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
Indacaterol and Glycopyrronium Bromide (QVA149)	QVA149 delivered once daily via single-dose dry powder inhaler.
Tiotropium	Tiotropium delivered once daily via HandiHaler® device.
Placebo	Placebo, delivered once daily via single-dose dry powder inhaler.

Other Adverse Events

	Indacaterol and Glycopyrronium Bromide (QVA149)	**Tiotropium**	**Placebo**
Total, other (not including serious) adverse events			
# participants affected / at risk	**11/77 (14.29%)**	**5/83 (6.02%)**	**4/77 (5.19%)**
Respiratory, thoracic and mediastinal disorders			

Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	**7/77 (9.09%)**	**5/83 (6.02%)**	**3/77 (3.90%)**
Cough † 1			
# participants affected / at risk	**5/77 (6.49%)**	**0/83 (0.00%)**	**1/77 (1.30%)**

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

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

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

Results Point of Contact:

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

No publications provided by Novartis

Publications automatically indexed to this study:

Beeh KM, Korn S, Beier J, Jadayel D, Henley M, D'Andrea P, Banerji D. Effect of QVA149 on lung volumes and exercise tolerance in COPD patients: the BRIGHT study. Respir Med. 2014 Apr;108(4):584-92. doi: 10.1016/j.rmed.2014.01.006. Epub 2014 Jan 21.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01294787 History of Changes
Other Study ID Numbers:	**CQVA149A2305** 2010-022721-14 (EudraCT Number)
Study First Received:	February 10, 2011
Results First Received:	November 29, 2012
Last Updated:	March 19, 2013
Health Authority:	United States: Food and Drug Administration Germany: Bunesinstitut fur Arzneimittel und Medizinprodukte Agencia Spain: Espanola de medicamentos y productos sanitarios