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Trial record **1 of 1** for: CQVA149A2326

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Comparison of Safety and Efficacy of the Combination Product QVA149A Against the Concurrent Administration of the Individual Components, QAB149 and NVA237, in Patients With Chronic Obstructive Pulmonary Disease (COPD) (BEACON)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01529632

First received: February 6, 2012
Last updated: January 16, 2014
Last verified: January 2014
History of Changes

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Results First Received: December 2, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
	Drug: QVA149

Interventions:	Drug: NVA237 Drug: QAB149 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
193 patients were randomized, with 187 of those completing the study. A total of 6 patients discontinued from the study.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Open-label, active QAB149 and NVA237 were administered during a 14-day period prior to randomization in order to stabilize patients and standardize baseline lung function. The patients were then randomized to either the fixed dose combination or free combination arms of blinded treatment in a 1:1 ratio and received study drug for 28 days.

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Participant Flow: Overall Study

	QVA149	**QAB149 + NVA237**
STARTED	**90**	**103**
COMPLETED	**87**	**100**
NOT COMPLETED	**3**	**3**

Administrative problem	**2**	**1**
Protocol Violation	**0**	**1**
Adverse Event	**1**	**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
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.
Total	Total of all reporting groups

Baseline Measures

	QVA149	QAB149 + NVA237	Total
Number of Participants [units: participants]	**90**	**103**	**193**
Age [units: years] Mean (Standard Deviation)	**65.6 (7.28)**	**64.2 (7.40)**	**64.9 (7.36)**
Gender [units: participants]			

Female	**32**	**44**	**76**
Male	**58**	**59**	**117**

Outcome Measures

Hide All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in 1 Second (FEV1) After 28 Days of Blinded Treatment [Time Frame: Day 29]

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) After 28 Days of Blinded Treatment
Measure Description	Spirometry was conducted according to internationally accepted standards. Trough FEV1 is defined as the average of the 23 hour 15 minute and 23 hour 45 minute post-dose FEV1 readings measured at day 29, after 28 days of treatment. Mixed model: Trough FEV1 = treatment + baseline FEV1 + FEV1 reversibility components + baseline smoking status + baseline ICS use + country + center (country) + error. Center was included as a random effect nested within country.
Time Frame	Day 29
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 includes the Full analysis Set patients with available data and without any major protocol deviations or criteria causing exclusion. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description

QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Measured Values

	QVA149	QAB149 + NVA237
Number of Participants Analyzed [units: participants]	**81**	**96**
Trough Forced Expiratory Volume in 1 Second (FEV1) After 28 Days of Blinded Treatment [units: Liters] Least Squares Mean (Standard Error)	**1.459 (0.0196)**	**1.465 (0.0180)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) After 28 Days of Blinded Treatment

2. Secondary: Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4 Hours at Day 1 [Time Frame: 0, 5, 15, and 30 minutes; and 1, 2, 3 and 4 hours post-dose at Day 1]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4 Hours at Day 1
Measure Description	Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4h at Day 1 was measured via spirometry conducted according to internationally accepted standards. Measurements were made at 0, 5, 15, and 30 minutes; and 1, 2, 3 and 4 hours post-dose. The standardized AUC FEV1 was calculated as the sum of trapezoids divided by the length of time. Mixed model used: AUC FEV1 = treatment + baseline FEV1 + FEV1 reversibility components + baseline smoking status + baseline ICS use + country + center (country) + error. Center was included as a random effect nested within country.
Time Frame	0, 5, 15, and 30 minutes; and 1, 2, 3 and 4 hours post-dose at 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.
The Per Protocol Set includes the Full analysis Set patients with available data and without any major protocol deviations or criteria causing exclusion. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Measured Values

	QVA149	**QAB149 + NVA237**
Number of Participants Analyzed [units: participants]	**83**	**97**
Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4 Hours at Day 1 [units: Liters] Least Squares Mean (Standard Error)	**1.597 (0.0125)**	**1.573 (0.0114)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4 Hours at Day 1

3. Secondary: Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4 Hours at Day 28 [Time Frame: 0, 5, 15, and 30 minutes; and 1, 2, 3 and 4 hours post-dose at Day 28]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4 Hours at Day 28
Measure Description	Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4h at Day 28 was measured via

	spirometry conducted according to internationally accepted standards. Measurements were made at 0, 5, 15, and 30 minutes; and 1, 2, 3 and 4 hours post-dose. The standardized AUC FEV1 was calculated as the sum of trapezoids divided by the length of time. Mixed model used: AUC FEV1 = treatment + baseline FEV1 + FEV1 reversibility components + baseline smoking status + baseline ICS use + country + center (country) + error. Center was included as a random effect nested within country.
Time Frame	0, 5, 15, and 30 minutes; and 1, 2, 3 and 4 hours post-dose at Day 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Per Protocol Set includes the Full analysis Set patients with available data and without any major protocol deviations or criteria causing exclusion. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Measured Values

	QVA149	**QAB149 + NVA237**
Number of Participants Analyzed [units: participants]	**80**	**92**
Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4 Hours at Day 28 [units: Liters] Least Squares Mean (Standard Error)	**1.575 (0.0200)**	**1.587 (0.0184)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) Area Under the Curve (AUC) 0-4 Hours at Day 28

4. Secondary: Peak Forced Expiratory Volume in 1 Second (FEV1) on Days 1 and 28 Post-dose [Time Frame: 5 min - 4 hr at Days 1 and 28]

Measure Type	Secondary
Measure Title	Peak Forced Expiratory Volume in 1 Second (FEV1) on Days 1 and 28 Post-dose
Measure Description	Spirometry was conducted according to internationally accepted standards. Peak FEV1 is the maximum FEV1 recorded in the period between 5 minutes and 4 hours post dose. Analysis of Covariance was carried out with a mixed model that used (period) baseline, defined as the value of FEV1 measured prior to the first study drug intake in the period, as a covariate.
Time Frame	5 min - 4 hr at Days 1 and 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Per Protocol Set includes the Full analysis Set patients with available data and without any major protocol deviations or criteria causing exclusion. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Measured Values

	QVA149	**QAB149 + NVA237**

Number of Participants Analyzed [units: participants]	**83**	**97**
Peak Forced Expiratory Volume in 1 Second (FEV1) on Days 1 and 28 Post-dose [units: Liters] Least Squares Mean (Standard Error)		
Day 1 (n=83, 97)	**1.668 (0.0132)**	**1.646 (0.0120)**
Day 28 (n= 80, 92)	**1.643 (0.0210)**	**1.654 (0.0194)**

No statistical analysis provided for Peak Forced Expiratory Volume in 1 Second (FEV1) on Days 1 and 28 Post-dose

5. Secondary: Time Course of Forced Expiratory Volume in One Second (FEV1) (Pre-dose to 4 Hours Post Dose) on Day 28 [Time Frame: -45 min, -15 min predose, 5 min, 30 min, 1 hr, 2hr, 3hr and 4 hr post-dose on Day 28]

Measure Type	Secondary
Measure Title	Time Course of Forced Expiratory Volume in One Second (FEV1) (Pre-dose to 4 Hours Post Dose) on Day 28
Measure Description	Time course of Forced Expiratory Volume in 1 second (FEV1) was measured at -45 min, -15 min predose, 5 min, 30 min, 1 hr, 2hr, 3hr and 4 hr post-dose on Day 28. FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation.
Time Frame	-45 min, -15 min predose, 5 min, 30 min, 1 hr, 2hr, 3hr and 4 hr post-dose on Day 28
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Per Protocol Set includes the Full analysis Set patients with available data and without any major protocol deviations or criteria causing exclusion. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Measured Values

	QVA149	QAB149 + NVA237
Number of Participants Analyzed [units: participants]	**78**	**91**
Time Course of Forced Expiratory Volume in One Second (FEV1) (Pre-dose to 4 Hours Post Dose) on Day 28 [units: Liters] Least Squares Mean (Standard Error)		
-45 min predose (n=76,90)	**1.452 (0.0197)**	**1.460 (0.0184)**
-15 predose (n=72,87)	**1.449 (0.0239)**	**1.430 (0.0227)**
5 min postdose (n=76,89)	**1.491 (0.0222)**	**1.514 (0.0206)**
30 min postdose (n=76,88)	**1.529 (0.0181)**	**1.544 (0.0166)**
1 hour postdose (n=77,90)	**1.584 (0.0204)**	**1.604 (0.0189)**
2 hours postdose (n=77,90)	**1.601 (0.0219)**	**1.624 (0.0203)**
3 hours postdose (n=78,91)	**1.576 (0.0211)**	**1.587 (0.0195)**
4 hours postdose (n=77,84)	**1.554 (0.0236)**	**1.556 (0.0228)**

No statistical analysis provided for Time Course of Forced Expiratory Volume in One Second (FEV1) (Pre-dose to 4 Hours Post Dose) on Day 28

6. Secondary: Change From Baseline in the Mean Daily, (Daytime and Nighttime Combined) Number of Puffs of Rescue Medication Used Over 28 Days of Treatment [Time Frame: Baseline and 28 days]

Measure Type	Secondary
Measure Title	Change From Baseline in the Mean Daily, (Daytime and Nighttime Combined) Number of Puffs of Rescue Medication Used Over 28 Days of Treatment
Measure Description	The number of puffs of rescue medication taken in the previous 12 hours was recorded in the Patient Diary in the morning and evening. The total number of puffs of rescue medication per day over the whole active treatment period was calculated and divided by the total number of days with non-missing rescue data to derive the mean daily number of puffs of rescue medication taken for the patient. If the number of puffs was missing for part of the day (either morning or evening) then a half day was used in the denominator.
Time Frame	Baseline and 28 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.
The Per Protocol Set includes the Full analysis Set patients with available data and without any major protocol deviations or criteria causing exclusion. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.

QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Measured Values

	QVA149	QAB149 + NVA237
Number of Participants Analyzed [units: participants]	**84**	**95**
Change From Baseline in the Mean Daily, (Daytime and Nighttime Combined) Number of Puffs of Rescue Medication Used Over 28 Days of Treatment [units: puffs] Mean (Standard Deviation)		
Baseline (day 1)	**2.24 (2.437)**	**2.04 (2.585)**
28 days after treatment	**1.85 (2.283)**	**1.70 (2.338)**

No statistical analysis provided for Change From Baseline in the Mean Daily, (Daytime and Nighttime Combined) Number of Puffs of Rescue Medication Used Over 28 Days of Treatment

7. Secondary: Change From Baseline in Percentage of Days With 'no Daytime Symptoms' Over 28 Days of Treatment [Time Frame: 28 days]

Measure Type	Secondary
Measure Title	Change From Baseline in Percentage of Days With 'no Daytime Symptoms' Over 28 Days of Treatment
Measure Description	The mean total symptom scores and mean individual symptom scores for the patient were calculated for the whole study period. The mean change from baseline in the total scores and in the individual scores were summarized by treatment and were analyzed for the percentage of 'nights with no nighttime awakenings'. The symptom variables for the whole active treatment period was analyzed using the similar MIXED model as for the primary endpoint, with the baseline FEV1 term being replaced by the respective baseline symptom variables.

Time Frame	28 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.
The Modified per protocol set (PPS) was defined post-DBL and included all patients with available data and without any major protocol deviations or criteria or GCP finding causing exclusion. Patients were analyzed according to the treatment to which they were randomized.

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Measured Values

	QVA149	**QAB149 + NVA237**
Number of Participants Analyzed [units: participants]	**82**	**93**
Change From Baseline in Percentage of Days With 'no Daytime Symptoms' Over 28 Days of Treatment [units: percentage of days] Mean (Standard Deviation)		
Baseline (day 1)	**6.2 (16.54)**	**3.9 (10.44)**
After 28 days of treatment	**9.3 (23.69)**	**6.0 (15.85)**

No statistical analysis provided for Change From Baseline in Percentage of Days With 'no Daytime Symptoms' Over 28 Days of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From day 1 to day 28 and additional 30 days follow up.
Additional Description	Safety Set included all patients who received at least one dose of study drug whether or not they were randomized.

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Serious Adverse Events

	QVA149	QAB149 + NVA237
Total, serious adverse events		
# participants affected / at risk	**4/90 (4.44%)**	**6/103 (5.83%)**
Cardiac disorders		
Pericarditis † [1]		
# participants affected / at risk	**0/90 (0.00%)**	**1/103 (0.97%)**
Infections and infestations		
Pneumonia † [1]		
# participants affected / at risk	**2/90 (2.22%)**	**0/103 (0.00%)**
Pyelonephritis † [1]		
# participants affected / at risk	**0/90 (0.00%)**	**1/103 (0.97%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Bronchial carcinoma † [1]		
# participants affected / at risk	**0/90 (0.00%)**	**2/103 (1.94%)**

Sarcoma † 1		
# participants affected / at risk	**0/90 (0.00%)**	**1/103 (0.97%)**
Renal and urinary disorders		
Nephrolithiasis † 1		
# participants affected / at risk	**0/90 (0.00%)**	**1/103 (0.97%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Pneumothorax † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Vascular disorders		
Aortic aneurysm † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	From day 1 to day 28 and additional 30 days follow up.
Additional Description	Safety Set included all patients who received at least one dose of study drug whether or not they were randomized.

Frequency Threshold

Threshold above which other adverse events are reported	1%

Reporting Groups

	Description
QVA149	QVA149 plus placebo once daily for 28 days.
QAB149 + NVA237	Indacaterol (QAB149) plus glycopyrronium bromide (NVA237) once daily for 28 days.

Other Adverse Events

	QVA149	QAB149 + NVA237
Total, other (not including serious) adverse events		
# participants affected / at risk	**20/90 (22.22%)**	**12/103 (11.65%)**
Gastrointestinal disorders		
Diarrhoea † [1]		
# participants affected / at risk	**1/90 (1.11%)**	**1/103 (0.97%)**
Oedema mouth † [1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Oral pain † [1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
General disorders		
Chest discomfort † [1]		
# participants affected / at risk	**2/90 (2.22%)**	**0/103 (0.00%)**
Infections and infestations		
Influenza † [1]		
# participants affected / at risk	**2/90 (2.22%)**	**1/103 (0.97%)**
Nasopharyngitis † [1]		
# participants affected / at risk	**7/90 (7.78%)**	**6/103 (5.83%)**
Injury, poisoning and procedural complications		

Ligament injury † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Musculoskeletal and connective tissue disorders		
Muscle spasms † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Myalgia † 1		
# participants affected / at risk	**2/90 (2.22%)**	**0/103 (0.00%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**1/90 (1.11%)**	**1/103 (0.97%)**
Neuropathy peripheral † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Somnolence † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Reproductive system and breast disorders		
Breast pain † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**3/90 (3.33%)**	**2/103 (1.94%)**
Cough † 1		

# participants affected / at risk	**4/90 (4.44%)**	**2/103 (1.94%)**
Dysphonia † 1		
# participants affected / at risk	**1/90 (1.11%)**	**1/103 (0.97%)**
Dyspnoea † 1		
# participants affected / at risk	**1/90 (1.11%)**	**2/103 (1.94%)**
Oropharyngeal pain † 1		
# participants affected / at risk	**1/90 (1.11%)**	**1/103 (0.97%)**
Pharyngeal oedema † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**
Rhinorrhoea † 1		
# participants affected / at risk	**1/90 (1.11%)**	**0/103 (0.00%)**

† 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 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: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
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Study First Received:	February 6, 2012
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Norway: Norwegian Medicines Agency
Sweden: Medical Products Agency