NOVARTIS

Full Novartis CTRD Template

Sponsor Novartis
Generic Drug Name Selurampanel
Therapeutic Area of Trial Partial onset seizures
Approved Indication Investigational
Protocol Number CBGG492A2207
Title A 12-week, multi-center, randomized, double-blind, placebo-controlled efficacy and safety study examining seizure frequency of BGG492 capsules administrated orally three times daily (TID) as adjunctive treatment in patients with partial onset seizures
Phase of Development Phase II
Study Start/End Dates 01 Jun 2010 to 26 Sept 2011
Study Design/Methodology Multi-center, multi-national, randomized, double-blind, placebo-controlled Phase II titration study comparing BGG492 immediate-release capsules (doses of 100mg, 150mg) to placebo capsules administrated orally three times daily (TID) in patients with refractory partial onset seizures. The study consisted of two cohorts: in Cohort 1 patients were randomized in a 1:2 ratio of placebo and BGG492 100 mg TID; in Cohort 2 patients were randomized in a 1:4 ratio of placebo and BGG492 150 mg TID. BGG492 was evaluated as an adjunct therapy, hence one or two pre-existing concomitant anti-epileptic drugs were allowed in Cohort 1 and one to three allowed in Cohort 2. Patients were required to have a history of uncontrolled partial seizures despite treatment with at least two different anti-epileptic drugs before entrance to the 1-4 week screening, 1-2 week titration, 2 4 week maintenance periods and 2-3 week taper off period.
Centres 23 centers in 7 countries: Germany (8), Hungary (13), Italy (5), Republic of Korea (27), Poland (3), Slovakia (6)United States (11)
Publication None

Outcome measures

All should match the corresponding section of the NLM ClinicalTrials.gov results record as much as possible.

Primary outcome measures(s)

- To detect the BGG dose-response as measured by a change in seizure frequency from the 4-week baseline period (Weeks -4 to -1) to the 4-week double-blind maintenance period (Weeks 7 to 10)

Secondary outcome measures(s)

- To evaluate the efficacy of BGG492 (100mg, 150 mg) administered orally TID compared to placebo assessed as change in seizure frequency from the 4-week baseline period (Weeks -4 to -1) to the 4-week double-blind maintenance period (Weeks 7 to 10)
- To evaluate the responder rate (responder defined as patients with a 50% or greater reduction in seizure frequency per 28 days from baseline) of BGG492 100 mg and BGG492 150 mg (administered orally TID) compared to the placebo during the 4-week (Week 7 – Week 10) double-blind maintenance period
- To evaluate the efficacy of BGG492 100 mg and BGG492 150 mg (administered orally TID) compared to placebo assessed as change in seizure frequency from the 4-week baseline period (Weeks -4 to -1) to the 10-week (Week 1 –Week 10) double-blind treatment evaluation phase
- To evaluate the proportion of seizure-free patients on BGG492 vs. placebo during the 4-week double-blind maintenance period (Week 7 – Week 10)
- To evaluate the safety and tolerability of BGG492 capsules compared to placebo
- To evaluate the PK of BGG492, all doses administered orally TID, in patients with partial onset seizures
- To evaluate the plasma levels of concomitant AEDs before and after treatment with BGG492

Test Product (s), Dose(s), and Mode(s) of Administration

Investigational drug:

- BGG492 100 and 150 mg capsules, oral TID

Reference therapy:

- Matching placebo capsules, oral TID

Statistical Methods

Analysis of the data was performed under the direction of Novartis personnel and was conducted as planned in the study protocol. A reporting and analysis plan was written and approved prior to database lock in order to provide more details of the analyses.

Seizure frequency per 28 days is the primary efficacy variable. Seizure frequency per 28 days was calculated as: (seizure frequency during a specified period / the number of days the seizure information were provided) x 28. Percent change in seizure frequency from baseline is defined as: 100*(Seizure frequency per 28 days during the baseline period - Seizure frequency per 28 days during a specified double-blind period)/Seizure frequency per 28 days during the baseline period.

The following hypothesis was tested for the primary objective: H_0: the BGG dose-response relationship is flat; H_a: BGG dose-response relationship shows a monotonically increasing trend with increasing doses. The multiple comparison approach (MCP), implemented in the MCP-Mod

methodology was used to detect dose-response relationship. The MCP-MOD was adopted in combination of an analysis of covariance (ANCOVA) model to allow for covariate adjustment. The natural log-transformed seizure frequency per 28 days was used in ANCOVA model as response variable. Because a small number of zero seizure counts were expected, a positive constant, chosen as 1/6, was added to all seizure frequencies before taking natural logarithms. The hypothesis test was based on four candidate models specified with selected fixed parameters to describe the candidate dose-response shapes. It was assumed that, for all 4 models, the percent reductions in seizure frequency over baseline are 20% and 50% for placebo and 150 mg BGG arms, respectively. Each candidate dose response shape had an optimal contrast test for dose-response signal associated with it. The tests utilized the least square means from the ANCOVA estimation. All tests were used to facilitate the selection of the most likely model and detection of the dose-response relationship, using a one sided testing, with an overall type one error of 2.5%, after appropriate adjustment for multiplicity.

The primary analysis was based on full analysis set.

Study Population: Inclusion/Exclusion Criteria and Demographics

The main criteria for inclusion are listed below:

- male and female patients aged 18 to 65 years inclusive
- diagnosis of epilepsy with partial seizures (≥ 2 years prior to screening) with or without secondary generalization (ILAE Classification of Epileptic Seizures, 1981)
- previous computer tomography (CT) or magnetic resonance imaging (MRI) within the 5 years prior to screening that ruled out progressive neurological changes and no physical examination suggestive of progressive neurological changes since the imaging procedure
- uncontrolled partial seizures despite treatment with at least two different AEDs within the last 2 years prior to screening (given concurrently or sequentially)
- at least 4 partial seizures (defined as simple partial seizures with motor signs, complex partial seizures, complex partial seizures with secondary generalization) during the 4-week prospective baseline and the 4 weeks immediately preceding the baseline

The main criteria for exclusion are listed below:

- History of Lennox-Gastaut syndrome, psychogenic seizures, status epilepticus or seizure clusters, and seizures caused by underlying medical illness, presence of only non-motor simple partial seizures, absences or myoclonic seizures
- Treatment with felbamate, vigabatrin, monoamine oxidase (MAO) inhibitors, tricyclic-antidepressants and narcotic analgesics, barbiturates (except for seizure control), intermittent benzodiazepines, L-dopa formulations and use of concomitant medication that are potential inhibitors of organic anion-transporting polypeptides (OATP) transporters
- Hypersensitivity to the study drug or to drugs of similar chemical classes, multiple drug allergies or severe drug reactions to an AED
- Use of other investigational drugs within 12 weeks prior to randomization
- Pregnant or nursing (lactating) women, women of childbearing potential
- Any of the following cardiovascular conditions: myocardial infarction and/or cerebrovascular accident (CVA), unstable angina pectoris hypertension uncontrolled by medication, cardiac failure, cardiac arrest, symptomatic bradycardia,or resting pulse < 50 beats per minute (bpm), sick sinus syndrome, sino-atrial heart block, second (Mobitz II) or third degree AV block, or pre-excitation syndrome abnormal electrocardiogram (ECG) parameters and arrhythmia

- Progressive CNS disease, psychotic disorder or suicide attempt
- Presence of visual field deficits and/or persistent double-vision
- Lipase values exceeding the upper limit of the normal range (ULN)
- Any of the following hepatic or biliary conditions: total bilirubin ≥ 2x ULN, unless in context of Gilbert's syndrome; aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (AP) ≥ 2x ULN; gamma-glutamyl-tranferase (GGT) ≥ 3x ULN; history of viral hepatitis
- Evidence of significant active hematological disease or renal impairment
- History alcohol or substance abuse
- Evidence of significant disease or disorder requiring current medical intervention/therapy
- History of malignancies other than localized basal cell carcinoma of the skin
- Patients treated with study medication in other clinical studies evaluating BGG492

Participant Flow

Patient disposition through end of 10-week double-blind treatment evaluation phase, by treatment group (Randomized set)

Disposition Primary reason	BGG492 150mg TID N=44 n (%)	BGG492 100mg TID N=24 n (%)	Placebo N=25 n (%)	Total N=93 n (%)
Screened				174
Randomized	44 (47.3)	24 (25.8)	25 (26.9)	93 (100.0)
Completed	37 (84.1)	20 (83.3)	24 (96.0)	81 (87.1)
Prematurely discontinued study medication	7 (15.9)	4 (16.7)	1 (4.0)	12 (12.9)
Adverse Event(s)	6 (13.6)	2 (8.3)	0	8 (8.6)
Subject withdrew consent	1 (2.3)	2 (8.3)	1 (4.0)	4 (4.3)

Percentages refer to the total number of patients randomized.
Reasons for discontinuation are presented in order of descending frequency in the BGG492 150 mg TID group.

Patient disposition through end of double-blind dose tapering phase, by treatment group (Randomized set)

Disposition Primary reason	BGG492 150mg TID N=44 n (%)	BGG492 100mg TID N=24 n (%)	Placebo N=25 n (%)	Total N=93 n (%)
Screened				174
Randomized	44 (47.3)	24 (25.8)	25 (26.9)	93 (100.0)
Completed	37 (84.1)	20 (83.3)	24 (96.0)	81 (87.1)
Prematurely discontinued study medication	7 (15.9)	4 (16.7)	1 (4.0)	12 (12.9)
Adverse Event(s)	6 (13.6)	2 (8.3)	0	8 (8.6)
Subject withdrew consent	1 (2.3)	2 (8.3)	0	3 (3.2)
Lost to follow-up	0	0	1 (4.0)	1 (1.1)

Percentages refer to the total number of patients randomized.
Reasons for discontinuation are presented in order of descending frequency in the BGG492 150 mg TID group.

Baseline Characteristics

Demographic summary, by treatment group (Randomized set)

Demographic Variable	BGG492 150 mg TID N=44	BGG492 100 mg TID N=24	Placebo N=25	Total N=93
Age (years)				
n	44	24	25	93
Mean (SD)	38.7 (10.62)	37.7 (10.67)	38.3 (12.32)	38.3 (11.00)
Median	38.5	37.0	36.0	37.0
Range	(22, 64)	(22, 60)	(21, 61)	(21, 64)
Age groups (years) [n (%)]				
18-40	24 (54.5)	17 (70.8)	15 (60.0)	56 (60.2)
41-65	20 (45.5)	7 (29.2)	10 (40.0)	37 (39.8)
Sex [n (%)]				
Male	21 (47.7)	12 (50.0)	14 (56.0)	47 (50.5)
Female	23 (52.3)	12 (50.0)	11 (44.0)	46 (49.5)
Race [n (%)]				
Caucasian	32 (72.7)	14 (58.3)	17 (68.0)	63 (67.7)
Black	0	0	1 (4.0)	1 (1.1)
Asian	11 (25.0)	9 (37.5)	7 (28.0)	27 (29.0)
Native American	1 (2.3)	0	0	1 (1.1)

Other	0	1 (4.2)	0	1 (1.1)
Ethnicity [n (%)]				
Hispanic/Latino	2 (4.5)	1 (4.2)	2 (8.0)	5 (5.4)
Other	42 (95.5)	23 (95.8)	23 (92.0)	88 (94.6)
Weight (kg)				
N	44	24	25	93
Mean (SD)	73.1 (16.21)	68.4 (14.14)	74.5 (17.21)	72.3 (15.99)
Median	70.6	67.4	73.0	70.0
Range	(50.0, 109.0)	(51.6, 103.0)	(50.2, 128.0)	(50.0, 128.0)
Height (cm)				
n	44	24	25	93
Mean (SD)	165.8 (24.83)	168.3 (10.51)	171.4 (10.36)	168.0 (18.69)
Median	168.5	168.0	172.0	169.0
Range	(63.0, 193.0)	(144.9, 187.0)	(151.0, 198.0)	(63.0, 198.0)
BMI (kg/m²)				
n	44	24	25	93
Mean (SD)	34.7 (47.39)	24.2 (4.60)	25.3 (4.94)	29.4 (32.96)
Median	24.1	23.5	24.8	24.1
Range	(17.3, 253.7)	(17.6, 38.8)	(19.0, 43.3)	(17.3, 253.7)
Region [n (%)]				
Asia	11 (25.0)	9 (37.5)	7 (28.0)	27 (29.0)
North America	6 (13.6)	2 (8.3)	3 (12.0)	11 (11.8)
Europe	27 (61.4)	13 (54.2)	15 (60.0)	55 (59.1)

Percentages refer to the total number of patients randomized

Demographic information and height are collected at Visit 1 (during the screening period)

Weight is the last value collected before first dose of study medication

BMI = weight(kg)/height(m)^2

Outcome measures

Primary Outcome Result(s)

Testing significance of candidate dose response models (Full analysis set)

Model	T statistic	Unadjusted p-value (one-sided)	Adjusted p-value (one-sided)*
Model 1	1.53	0.0650	0.0985
Model 2	1.62	0.0547	0.0839
Model 3	1.63	0.0538	0.0826
Model 4	1.57	0.0607	0.0926

Model: log (seizure frequency + 1/6) per 28 days during 4 week (Week 7- Week 10) = treatment + region + AED strata at baseline + log (baseline seizure frequency + 1/6) + error.

* Models with an adjusted one-sided p-value < 0.025 are significantly different from constant dose-response (i.e. no dose response) model.

Secondary Outcome Result(s)

Between-treatment analysis of change in total partial seizure frequency per 28 days from baseline to the 4-week (Week 7 to Week 10) double-blind maintenance period, by treatment group (Full analysis set)

		LS Mean in log scale	Difference in log scale		
Treatment	**n**	**LS Mean (SE)**	**LS Mean**	**(95% CI)**	**p-value**
BGG492 150 mg TID (N=44)	39	1.99 (0.204)	-0.47	(-1.11, 0.17)	0.1051
BGG492 100 mg TID (N=24)	22	2.17 (0.257)	-0.29	(-1.02, 0.44)	0.3765
Placebo (N=25)	24	2.46 (0.248)			

	% reduction over placebo	
	% reduction	**(95% CI)**
BGG492 150 mg TID (N=44)	37.32	(-18.90, 66.95)
BGG492 100 mg TID (N=24)	25.08	(-55.40, 63.88)

Baseline refers to the period of 28 days from Week -4 to Day 1 (Visit 3).

Least square means and the associated standard errors, confidence intervals, and p-values are from an analysis of covariance (ANCOVA) model with log (seizure frequency + 1/6) as response variable, with treatment, region and AED strata at baseline as factors and with log (baseline seizure frequency + 1/6) as a covariate.

The LS mean difference in log scale is (LS mean of BGG log seizure frequency — LS mean of placebo log seizure frequency).

The % reduction is calculated as 100*(1 - Exp{LS mean difference in log scale}).

Change and percent change in total partial seizure frequency per 28 days from baseline to the 4-week (Week 7 to Week 10) double-blind maintenance period, by treatment group (Full analysis set)

Time period	**Statistics**	**BGG492 150 mg TID N=44**	**BGG492 100 mg TID N=24**	**Placebo N=25**
Baseline (Weeks -4 to -1)	n	39	22	24
	Mean (SD)	29.3 (56.34)	25.7 (40.61)	25.7 (41.53)
	Median	9.0	11.2	10.1
	Range	(3.7,316.7)	(3.9,181.5)	(3.7,177.7)
Week 7 to Week 10	n	39	22	24
	Mean (SD)	17.7 (31.96)	20.7 (38.40)	22.5 (37.52)
	Median	6.2	9.2	13.5
	Range	(0.0,167.0)	(0.0,180.6)	(0.0,184.0)
Change from baseline	n	39	22	24
	Mean (SD)	11.6 (43.87)	5.0 (9.88)	3.2 (14.70)
	Median	2.1	2.4	1.7
	Range	(-42.7,228.8)	(-7.9,37.7)	(-15.8,63.7)
Percent change from baseline (%) [1]	n	39	22	24
	Mean (SD)	24.6 (51.36)	26.4 (37.04)	-6.2 (91.52)
	Median	30.0	33.4	14.3
	Range	(-88.5,100.0)	(-41.0,100.0)	(-355.2,100.0)
	P-value [2]	0.1859	0.1974	

Change in seizure frequency from baseline = B-T, B=Seizure frequency per 28 days during baseline period, T=Seizure frequency per 28 days during the 4 week double-blind period.

Percent change in seizure frequency from baseline = 100 (B-T)/B, B=Seizure frequency per 28 days during baseline period, T=Seizure frequency per 28 days during the 4 week double-blind period.

A positive change indicates a reduction from baseline.

Seizure frequency per 28 days is calculated as: (seizure frequency during the specified double-blind period / the number of days the seizure information were provided) x 28.

Only patients with both baseline and corresponding post-baseline values are included.

[1] Only patients with non-zero seizure frequency count at baseline are included in percent change calculation.

[2] P-values are from Wilcoxon rank-sum test on the median percent change from baseline for the BGG groups and placebo group.

Responder rate during the 4-week (Week 7 to Week 10) double-blind maintenance period, by treatment group (Full analysis set)

Treatment	Total n [1]	Responder [2] n (%)	Odds ratio [3]	95% interval for odds ratio	P-value [4]
BGG492 150 mg TID (N=44)	39	14 (35.9)	2.86	(0.79, 10.31)	0.1081
BGG492 100 mg TID (N=24)	22	5 (22.7)	1.60	(0.36, 7.12)	0.5403
Placebo (N=25)	24	4 (16.7)			

[1] n is the number of patients with non-missing seizure information during the specified period.

[2] Responder is defined as patients with a 50% or greater reduction in total partial seizure frequency per 28 days from baseline.

[3] The odds of a BGG treated patient being a responder relative to the odds of a placebo treated patient being a responder based on the logistic regression model that uses treatment, region, AED strata at baseline and log (baseline seizure frequency + 1/6) as explanatory variables.

[4] P-value of treatment comparison to placebo based on the logistic regression model.

PK report delayed due to sample import license issues to the analytical lab in India and will be available in November. CTRD will be updated to include PK data once the report is final.

Safety Results

Incidence of adverse events during the 10-week double-blind treatment evaluation phase (>5% of any treatment group), regardless of study drug relationship, by primary system organ class and treatment group

Primary system organ class	BGG492 150 mg TID N=44 n (%)	BGG492 100 mg TID N=24 n (%)	Placebo N=25 n (%)	Total N=93 n (%)
Any primary system organ class	31 (70.5)	15 (62.5)	15 (60.0)	61 (65.6)
Eye disorders	3 (6.8)	0	0	3 (3.2)
Gastrointestinal disorders	7 (15.9)	3 (12.5)	4 (16.0)	14 (15.1)
General disorders and administration site conditions	10 (22.7)	3 (12.5)	2 (8.0)	15 (16.1)
Infections and infestations	0	3 (12.5)	5 (20.0)	8 (8.6)
Injury, poisoning and procedural complications	0	2 (8.3)	0	2 (2.2)
Nervous system disorders	20 (45.5)	7 (29.2)	4 (16.0)	31 (33.3)
Psychiatric disorders	0	0	4 (16.0)	4 (4.3)
Vascular disorders	0	2 (8.3)	0	2 (2.2)

Primary system organ classes are presented alphabetically

A patient with multiple AEs within a SOC and under one treatment is counted only once in the SOC

Number (%) of patients reporting common AEs during the 10-week double-blind treatment evaluation phase (>5% of any treatment group), by preferred term and treatment group (Safety set)

Preferred term	BGG492 150mg TID N=44 n (%)	BGG492 100mg TID N=24 n (%)	Placebo N=25 n (%)	Total N=93 n (%)
Any primary system organ class	31 (70.5)	15 (62.5)	15 (60.0)	61 (65.6)
Dizziness	14 (31.8)	3 (12.5)	1 (4.0)	18 (19.4)
Somnolence	7 (15.9)	1 (4.2)	1 (4.0)	9 (9.7)
Fatigue	5 (11.4)	1 (4.2)	1 (4.0)	7 (7.5)
Gait disturbance	3 (6.8)	0	0	3 (3.2)
Nausea	3 (6.8)	2 (8.3)	2 (8.0)	7 (7.5)
Headache	2 (4.5)	1 (4.2)	2 (8.0)	5 (5.4)
Hypertension	2 (4.5)	2 (8.3)	0	4 (4.3)
Nasopharyngitis	1 (2.3)	1 (4.2)	2 (8.0)	4 (4.3)

Preferred terms are sorted by descending order of incidence in the BGG492 150 mg TID group.

Deaths, other serious or related discontinuations during the 10-week double-blind treatment evaluation phase (Safety set)

	BGG492 150 mg TID N=44 n (%)	BGG492 100 mg TID N=24 n (%)	Placebo N=25 n (%)	Total N=93 n (%)
Patients with AE(s)	31 (70.5)	15 (62.5)	15 (60.0)	61 (65.6)
Serious or other significant events				
Death	0	0	0	0
SAE(s) (non fatal)	3 (6.8)	3 (12.5)	0	6 (6.5)
Discontinued due to AE(s)	6 (13.6)	2 (8.3)	0	8 (8.6)
Discontinued due to SAE(s)	2 (4.5)	2 (8.3)	0	4 (4.3)

Patients may be counted in more than one category.

Incidence of serious adverse events during the 10-week double-blind treatment evaluation phase, regardless of study drug relationship, by primary system organ class, preferred term and treatment group (Safety set)

Primary system organ class Preferred term	BGG492 150 mg TID N=44 n (%)	BGG492 100 mg TID N=24 n (%)	Placebo N=25 n (%)	Total N=93 n (%)
Any primary system organ class-Total	3 (6.8)	3 (12.5)	0	6 (6.5)
Blood and lymphatic system disorders -Total	1 (2.3)	0	0	1 (1.1)
Iron deficiency anaemia	1 (2.3)	0	0	1 (1.1)
Gastrointestinal disorder -Total	1 (2.3)	0	0	1 (1.1)
Tongue oedema	1 (2.3)	0	0	1 (1.1)
General disorders and administration site conditions -Total	1 (2.3)	0	0	1 (1.1)
Feeling drunk	1 (2.3)	0	0	1 (1.1)
Infections and infestations -Total	0	1 (4.2)	0	1 (1.1)
Urinary tract infection	0	1 (4.2)	0	1 (1.1)
Nervous system disorders -Total	2 (4.5)	2 (8.3)	0	4 (4.3)
Balance disorder	1 (2.3)	0	0	1 (1.1)
Convulsion	1 (2.3)	1 (4.2)	0	2 (2.2)
Dizziness	1 (2.3)	0	0	1 (1.1)
Headache	0	1 (4.2)	0	1 (1.1)

Primary system organ classes are presented alphabetically; preferred terms are sorted within primary system organ class in descending order of frequency based on BGG492 150 mg TID group.

A patient with multiple AEs within a SOC and under one treatment is counted only once in the SOC.

Incidence of adverse events causing study drug discontinuation during the 10-week double-blind treatment evaluation phase, regardless of study drug relationship, by primary system organ class, preferred term and treatment group (Safety set)

Primary system organ class Preferred term	BGG492 150mg TID N=44		BGG492 100mg TID N=24		Placebo N=25		Total N=93	
	n	(%)	n	(%)	n	(%)	n	(%)
Any primary system organ class-Total	6	(13.6)	2	(8.3)	0		8	(8.6)
Ear and labyrinth disorders-Total	1	(2.3)	0		0		1	(1.1)
Vertigo	1	(2.3)	0		0		1	(1.1)
Eye disorders-Total	2	(4.5)	0		0		2	(2.2)
Diplopia	1	(2.3)	0		0		1	(1.1)
Vision blurred	1	(2.3)	0		0		1	(1.1)
Gastrointestinal disorders-Total	3	(6.8)	0		0		3	(3.2)
Nausea	2	(4.5)	0		0		2	(2.2)
Tongue oedema	1	(2.3)	0		0		1	(1.1)
General disorders and administration site conditions-Total	4	(9.1)	0		0		4	(4.3)
Gait disturbance	2	(4.5)	0		0		2	(2.2)
Fatigue	1	(2.3)	0		0		1	(1.1)
Feeling drunk	1	(2.3)	0		0		1	(1.1)
Irritability	1	(2.3)	0		0		1	(1.1)
Nervous system disorders-Total	5	(11.4)	2	(8.3)	0		7	(7.5)
Dizziness	4	(9.1)	0		0		4	(4.3)
Balance disorder	1	(2.3)	0		0		1	(1.1)
Convulsion	1	(2.3)	1	(4.2)	0		2	(2.2)
Headache	1	(2.3)	1	(4.2)	0		2	(2.2)

Primary system organ classes are presented alphabetically; preferred terms are sorted within primary system organ class in descending order of frequency based on BGG492 150 mg TID group. A patient with multiple AEs within a SOC and under one treatment is counted only once in the SOC.
Other Relevant Findings Not applicable
Date of Clinical Trial Report 27-Jun-2012
Date Inclusion on Novartis Clinical Trial Results Database 25 Sep 2012
Date of Latest Update