Sponsor Novartis
Generic Drug Name: **N/A**
Therapeutic Area of Trial Moderate persistent asthma
Approved Indication Investigational – not approved
Protocol Number QAV680A2201E1

Title

A randomized, double-blind, parallel group study to compare the pharmacodynamics/efficacy, safety and pharmacokinetics of QAV680 versus placebo in patients with moderate persistent asthma

Phase of Development

Phase II

Study Start/End Dates

05 Apr 2010 to 02 Sep 2010

Early termination date: 25 Aug 2010
The study was discontinued by Novartis due to conflicting priorities.

Study Design/Methodology

A multicenter, randomized, double blind, parallel group study to compare the pharmacodynamic/efficacy effects of QAV680 500 mg q.i.d compared to placebo when administered for 28 days to patients with moderate persistent asthma. The study consisted of a 28-day screening period (Day -42 to Day -15), a placebo washout period (Day -14 to Day -1), a 28 day treatment period followed by a study completion evaluation.

Centers

3 Centers in 2 countries: USA (2 centers), Germany (1 center)

Publication

N/A

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

QAV680 500mg (5 x 100mg capsules) or matched placebo capsules. oral

Statistical methods: No formal statistical testing was performed on any of the data collected in this study due to the early termination of the study.

Study Population: Inclusion/Exclusion Criteria and Demographics

Demographics: Male and female patients aged between 18 and 65 years inclusive

Criteria
Inclusion Criteria:

- Patients with moderate persistent asthma
- FEV1 ≥ 60% and ≤ 90% of the predicted normal value at baseline after the placebo run-in period had completed
- Patients had to have demonstrated an increase of ≥12% and or 200 mL in FEV1 over their prebronchodilator value post short acting β2-agonist (400µg inhaled Salbutamol)

Exclusion Criteria:

- Smokers
- Any significant disease or illness, other than asthma

Participant Flow

Table 10-1 Patient disposition – n (%) of patients (Safety analysis set)

	QAV680	Placebo	All patients
Patients			
Randomized	6 (100%)	5 (100%)	11 (100%)
Completed	5 (83%)	3 (60%)	8 (73%)
Discontinued	1 (17%)	2 (40%)	3 (27%)
Main cause of discontinuation			
Study termination	1 (17%)	2 (40%)	3 (27%)

Baseline Characteristics

		QAV680 N=6	Placebo N=5	All patients N=11
Age (years)	Mean (SD)	41.5 (14.38)	39.8 (11.48)	40.7 (12.52)
	Range	24-58	29-59	24-59
Gender - n(%)	Male	6 (100%)	5 (100%)	11 (100%)
Race - n(%)	Caucasian	5 (83%)	4 (80%)	9 (82%)
	Black	1 (17%)	1 (20%)	2 (18%)
Weight (kg)	Mean (SD)	106.8 (19.03)	94.6 (17.08)	101.3 (18.39)
	Range	73.0-123.0	79.5-116.7	73.0-123.0
Height (cm)	Mean (SD)	179 (8.1)	181 (4.8)	180 (6.5)
	Range	170-190	173-186	170-190

Safety Results

Adverse Events by System Organ Class

		QAV680 500 mg	Placebo
		N=6	N=5
		n (%)	n (%)
Subjects with AE(s)		4 (67)	2 (40)
System organ class	**Preferred term**		
Congenital, familial and genetic disorders	Dysplastic naevus syndrome	1 (17)	0
Gastrointestinal disorders	Nausea	0	1 (20)
General disorders and administration site conditions	Pyrexia	1 (17)	0
Infections and infestations	Urinary tract infection	1 (17)	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	0	1 (20)
Neoplasms benign, malignant and unspecified	Squamous cell carcinoma of skin	1 (17)	0
Nervous system disorders	Headache	1 (17)	0
Skin and subcutaneous tissue disorders	Blood blister	1 (17)	0

Serious Adverse Events and Deaths

	QAV680 500 mg	Placebo
No. (%) of subjects studied	N=6	N=5
No. (%) of subjects with AE(s)	4 (67)	2 (40)
Number (%) of subjects with serious or other significant events	0 (0.0)	0 (0.0)
Death	0 (0.0)	0 (0.0)
SAE(s)	0 (0.0)	0 (0.0)
Discontinued due to SAE(s)	0 (0.0)	0 (0.0)

Other Relevant Findings

N/A

Date of Clinical Trial Report

17-Oct-2011

Date Inclusion on Novartis Clinical Trial Results Database

25 July 2012

Date of Latest Update

25 July 2012