Sponsor Novartis
Generic Drug Name Secukinumab (AIN457)
Therapeutic Area of Trial Crohns Disease
Approved Indication Investigational

Protocol Number

CAIN457A2202E1

Title

A 52-week open label extension study to evaluate the safety and tolerability of AIN457 (anti IL-17 monoclonal antibody) in patients with moderate to severe Crohn's disease.

Phase of Development

Phase 2

Study Start/End Dates

FPFV: 30-Aug-2009
LPLV: 19-Aug-2010

None of the patients received AIN457 for the full study period of 52 weeks, as the study was terminated early due to lack of efficacy as determined by futility analysis on occasion of a scheduled interim analysis in the core trial.

Study Design/Methodology

This was a multicenter, open-label, non-randomized trial without comparator that provided active treatment over 48 weeks to those patients who either completed the core study or, after amendment 1 was implemented, completed at least the primary endpoint Visit 8 (Day 43) of the core study. All patients received 3 mg/kg AIN457 q4wk in the extension study.

Centres

6 centers in 3 countries USA (3), Canada (3), Poland (1)

Publication

None

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

AIN457 150 mg lyophilizate vials were prepared by Novartis and were supplied to the investigator as open label bulk medication. All patients in this study received 3 mg/kg of AIN457 i.v. q4wk.

Statistical Methods

Safety and tolerability variables including vital signs, AEs, ECG and laboratory variables, as well as background and demographic information, were analyzed in a descriptive manner over time. Descriptive statistics of the CDAI over time and frequency tables of the number of patients in remission (CDAI<150) over time were provided as exploratory long-term efficacy assessments. Graphs of the average CDAI time course over time were displayed. Pharmacokinetics of AIN457 were described but not analyzed

Study Population: Inclusion/Exclusion Criteria and Demographics

Main Inclusion Criteria:

- Patients who participate and complete the core CAIN457A2202 study up to and including Visit 11 (end of study) may enter the extension study upon signing the informed consent

Main Exclusion criteria

- Patients for whom continue treatment with AIN457 is not considered appropriate by the treating physician
- Patients who were non-compliant or who demonstrated a major protocol violation in the core CAIN457A2202 study
- Patient who discontinued from the core CAIN457a2202 study before end of study

Participant Flow

	Total n (%)
Patients	
Randomized	7
Expose	7
Completed	0
Discontinued	7
Primary reason for premature discontinuation	
Adverse event(s)	0
Subject withdrew consent	0
Protocol deviation	0
Abnormal test procedure result(s)	0
Unsatisfactory therapeutic effect	0
Lost to follow-up	0
Abnormal laboratory value(s)	0
Death	0
Early termination	7

Baseline Characteristics

		Total N=7
Age (years)	Mean	44.9
	SD	15.8
	Median	47
	Min - Max	27-72
Sex – (%)	Male	6 (86%)
	Female	1 (14%)
Race – n (%)	Caucasian	7 (100%)
	Black	0
	Asian	0
	Other	0

Safety Results

Adverse Events by System Organ Class

	AIN457 3mg/kg n=7 n (%)
Patients with AE(s)	3 (42.9)
System organ class	
Gastrointestinal disorders	2 (28.6)
General disorders and administration site conditions	1 (14.3)
Infections and infestations	1 (14.3)
Musculoskeletal and connective tissue disorders	1 (14.3)
Psychiatric disorders	1 (14.3)

10 Most Frequently Reported AEs Overall by Preferred Term n (%)

	AIN457 3mg/kg N=7 n(%)
Patients with AE(s)	3 (42.9)
Preferred term	
Abdominal distension	1 (14.3)
Depression	1 (14.3)
Gastroesophageal reflux disease	1 (14.3)
Influenza like illness	1 (14.3)
Musculoskeletal pain	1 (14.3)
Nausea	1 (14.3)
Upper respiratory tract infection	1 (14.3)
Vomiting	1 (14.3)

Serious Adverse Events and Deaths

None

Other Relevant Findings

Not applicable

Date of Clinical Trial Report

19-Sep-2011 (content final)

Date Inclusion on Novartis Clinical Trial Results Database

29 March 2012

Date of Latest Update

29 March 2012