Sponsor

Novartis Pharma AG

Generic Drug Name

SBR759

Therapeutic Area of Trial

Chronic Kidney Disease (CKD)

Approved Indication

Investigational

Protocol ID Number

CSBR759A2305

Title

A facilitated access open-label, non-randomized, multi-center long-term safety and efficacy study in Chronic Kidney Disease patients treated with SBR759 who have completed previous SBR759 studies

Phase of Development

Phase III

Study Start/End Dates

09-Sep-2009 to 29-Jul-2010

Study Design/Methodology

This open-label, non-randomized multi-center study used an umbrella protocol designed to collect long-term safety and efficacy data from Chronic Kidney Disease patients who have been treated with SBR759 in previous studies (CSBR759A2201/2202).

During the study, patients had to continue treatment with the same dose of SBR759 as in their previous SBR759 study. SBR759 dose was adjusted based on patient's local laboratory phosphate levels. Dose changes had to be applied to bring patients within the target serum phosphate range. Study visits, at which patients vital signs and laboratory values were assessed, occurred quarterly and drug supply was dispensed monthly, or if needed for dose adjustment, at any time during the study.

Two rounds of data analysis were planned for the study. An interim analysis was planned two years post study initiation and a final analysis was planned at study completion.

Novartis decided to prematurely terminate the CSBR759A2305 as the results from the 12 weeks core period of study CSBR759A2201 did not meet the primary objective of effectively lowering phosphate levels in contrast to the Asian CSBR759A2202 study .

Centers

15 centers in 9 countries: Australia (1), Belgium (2), France (1), Italy (4), Norway (1), Sweden (2), Switzerland (1), Taiwan (2) and USA (1)

Publication

None

Date of Clinical Trial Report

08-Mar-2011

Date Inclusion on Novartis Clinical Trial Results Database

Oct 10, 2011

Date of Latest Update

Oct 10, 2011