

Report According to § 42 b (2) German Drug Law

Protocol No.: GB29298

Protocol Title: GB29298- A randomized, double-blind, placebo-controlled, Phase II study to assess the efficacy and safety of oral vismodegib for the treatment of idiopathic pulmonary fibrosis.

Date of Reports: NA

Study Sponsor(s) F. Hoffmann – La Roche Ltd., Basel, Switzerland

Name of Active Substance: Vismodegib

Name of Medicinal Product: Erivedge®

Study Dates: Health Authority Approval: 04.09.2014
Premature end: 17.07.2015

Trial Phase: II

Indication: Idiopathic Pulmonary Fibrosis

Study Interruptions 08.09.2014. Please see below.

Premature End: 17.07.2015. No patients were enrolled in clinical trial GB29298 entitled, “A randomized, double-blind, placebo-controlled, Phase II study to assess the efficacy and safety of oral vismodegib for the treatment of idiopathic pulmonary fibrosis.”
Enrollment was postponed to allow the Roche team the opportunity to further review the evolving IPF environment in order to provide the highest quality clinical trial. The study has subsequently been terminated. A new clinical trial in this indication was approved: GB29764 entitled “A single arm, multicenter, open-label, phase 1b study to assess the safety and tolerability of oral vismodegib in combination with pirfenidone in patients with idiopathic pulmonary fibrosis.”

Number of Subjects Planned 129

Planned/Analyzed: 0