Phase 2 Program of AntiCoagulation via Inhibition of FXIa by the oral Compound BAY 2433334 – noncardioembolic Stroke study, PACIFIC STROKE)

Principal Investigator:	PD Dr. med Georg Kägi
Status:	ongoing, Recruitment stopped
Project Start:	2020
Project End:	2022
Trial Design /Class:	Multicenter, randomized, placebo-controlled, double-blind, parallel group, dose-finding Phase 2, Category: C
Number of Patient:	1800
Centers:	23 countries study: Austria, Australia, Belgium, Bulgaria, China,Czech Rep, Denmark, Finland, France, Germany, Hungary, Italy, Japan, Netherlands, Poland, Portugal, Russia, Slovakia, Spain, Sweden, Switzerland, UK, US
Sponsor/Partner:	Bayer AG
Funding:	Industry Sponsor – Bayer AG

Summary:

This study will assess the dose response of BAY 2433334 in order to determine the dose that is efficacious and safe and that can be used in a Phase 3 study in the same indication. Current guidelines recommend antiplatelet therapy for patients after a non-cardioembolic ischemic stroke / transient ischemic attack (TIA). The addition of a FXIa inhibitor on top of antiplatelet therapy is expected to lead to a benefit regarding secondary prevention of stroke combined with no or only minimal increase in bleeding and especially no increase in major bleeding.

Objectives:

Primary Efficacy Objective
to assess the dose response of 3 different doses of BAY 2433334 compared to placebo in reducing the composite of symptomatic ischemic strokes and covert brain infarcts detected by magnetic resonance imaging (MRI) as well as other cerebro- and cardiovascular endpoints in participants with an acute noncardioembolic ischemic stroke and who are treated with antiplatelet therapy.

Primary Safety Objective
to evaluate whether the incidence of bleeding for BAY 2433334 is similar compared to placebo in participants with an acute non-cardioembolic ischemic stroke and who are treated with antiplatelet therapy.