

Press release: AdvanceCOR GmbH announces favourable results of a clinical phase II study on Revacept vs. placebo in patients with symptomatic stenosis of the carotid artery suffering from ischemic stroke

Munich, January 2020

AdvanceCOR GmbH announces the successful completion and positive results of the first phase II study with Revacept®. This phase II study in 158 patients with symptomatic carotid artery stenosis (transient ischemic attack (TIA) or stroke, [NCT01645306](#)) investigated micro-infarctions in the brain by diffusion-weighted magnetic resonance imaging (DWI-MRI) tomography, micro-embolic signals in brain arteries and clinical results. The study was carried out in double-blinded and randomized fashion with two doses of Revacept and a placebo control group. All patients were under guideline conform anti-platelet therapy and underwent carotid artery endarterectomy (CEA; 80.4% of all patients), carotid artery stenting (CAS, 7.6%) or best medical therapy (BMT, 12.0%). Safety endpoints were bleedings according to the RE-LY criteria and further safety aspects, and were investigated for 90 days and with a 365 day telephone interview follow-up in an explorative manner. 53 patients received 120 mg Revacept, 54 patients 40 mg Revacept and 51 patients placebo by a single IV infusion.

The number of new peri-interventional infarctions in the brain (DWI-MRI) was reduced by 46% in the 120 mg Revacept group compared to placebo (10% reduction with Revacept 40 mg). 23% fewer patients had new brain infarcts with 120 mg Revacept compared to placebo-treated patients (no positive effect with 40 mg Revacept). TCD-MES could not be analysed appropriately, because their incidence upon study inclusion was less than 50% in all groups. Clinically apparent ischemic strokes and TIA trended to be reduced up to 90 days after the intervention: 7.5% of patients in the Revacept 120 mg group experienced a recurrent TIA or stroke, and 9.8% in the placebo group (24% risk reduction). Most of the bleedings were postoperative bleedings which tended to be more frequent in placebo-treated patients compared to Revacept. Major bleeding complications (according to the RE-LY criteria) occurred in 4 patients (7.5%) in the 120 mg Revacept group, 6 patients (11.1%) in the 40 mg Revacept group and 5 patients (9.8%) in the placebo group. One patient had intra-cerebral bleeding with 40 mg Revacept, and one with placebo, one sub-arachnoidal bleeding with placebo.

The trial was conceived as exploratory study not powered for statistical significance. Therefore, observed effects failed to reach statistical significance. In summary, Revacept has the potential to reduce ischemic brain infarctions due to the underlying atherothrombosis and the peri-interventional stroke risk at short term with a prolonged protection after a single IV infusion. Revacept might be useful for secondary prophylaxis of ischemic complications in patients with cerebro-vascular disease after stroke and also during surgical or interventional procedures.

A second investigator-initiated phase II clinical study in patients with coronary artery disease (NCT 03312855, EudraCT 2015-000686-32) is being carried out by the teams of Prof. Adnan Kastrati, German Heart Center, Munich and of Prof. Steffen Massberg, Großhadern Clinic of the Ludwig-Maximilian University, and other clinical entities who cooperate within the German Center for Cardiovascular Diseases (DZHK). In this randomized, double-blinded placebo controlled study, almost all anticipated 332 patients have already been recruited. No increase in bleeding complications and also a signal for reduced ischemic complications (myocardial infarction and stroke) was noted compared to similar patient cohorts from previous studies. Due to the blinded study design, the final analysis of efficacy will be available after the end of the study.

About Revacept

Revacept is a human Fc fusion protein, which prevents the local activation of platelets at sites of vascular injury, acting like a "vascular coating". Efficacy studies showed that Revacept resulted in significantly reduced thrombus formation at these sites. However, systemic hemostasis is not affected.

In a first in man study, all doses were well tolerated, no drug-related adverse events occurred, bleeding time was not prolonged. The expected inhibitory effect on platelet aggregation was measured in a dose-dependent fashion in the blood of the individuals whereas no bleeding complications nor platelet depletion (thrombopenia) were observed.

About AdvanceCOR GmbH

AdvanceCOR GmbH is a biotechnology company located in Martinsried near Munich, Germany. AdvanceCOR owns several clinical and preclinical projects generated from its own scientific program or from the university groups of the company's founders.

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