Media Release
February 5, 2019

Idorsia announces the first patient recruited into REACT – the Phase 3 registration study with clazosentan

• REACT assesses the efficacy and safety of intravenous clazosentan for the prevention of clinical deterioration due to vasospasm-related delayed cerebral ischemia following aneurysmal subarachnoid hemorrhage (aSAH)
• On June 18, 2018, Idorsia announced the plans for REACT and held an investor webcast, please refer to the documentation on our corporate website for more information

Allschwil, Switzerland – February 5, 2019
Idorsia Ltd (SIX: IDIA) today announced that the first patient has been included into REACT, a Phase 3 registration study to investigate the efficacy and safety of clazosentan for the prevention of clinical deterioration due to vasospasm-related delayed cerebral ischemia in patients following an aneurysmal subarachnoid hemorrhage.

Guy Braunstein, MD and Head of Global Clinical Development, commented:
“REACT builds on the learnings from previous clinical studies with clazosentan, which have served to identify the optimal treatment dose for Phase 3 evaluation and the characteristics and management of the patients that are most likely to benefit from this treatment. It is very satisfying to have achieved the milestone of first patient included into the study. It’s now full steam ahead to recruit 400 patients.”

Notes to the editor

About clazosentan
Several studies have built our understanding of clazosentan, an intravenous endothelin receptor antagonist, regarding its impact on preventing or reversing cerebral vasospasm. These studies suggest that clazosentan has the potential to prevent vasospasm-related delayed cerebral ischemia and to decrease the need for invasive neurovascular intervention. Clazosentan was granted orphan status in Europe in 2003 and in the US in 2006.

About the REACT study
REACT is a prospective, multi-center, double-blind, randomized, placebo-controlled, parallel-group, Phase 3 study to assess the efficacy and safety of clazosentan in preventing clinical deterioration due to vasospasm-related delayed cerebral ischemia, in adult patients with aSAH. Approximately 400 patients, regardless of whether their hemorrhage has been treated with surgical clipping or endovascular coiling are expected to be enrolled. Patients will be enrolled from 100 trial sites across 15 countries and will be randomized to either 15 mg/hr clazosentan or placebo for a treatment period of up to 14 days. The study is expected to run for over two years.

REACT will enroll aSAH patients identified as being at high-risk of developing delayed ischemic neurological deficit because of high volume of their hemorrhage, as assessed by CT scan on hospital admission. Patients experiencing asymptomatic (or minimally symptomatic) moderate to severe cerebral vasospasm within 14 days of the aneurysm-rupture may also be included.

About aneurysmal subarachnoid hemorrhage and cerebral vasospasm
Aneurysmal subarachnoid hemorrhage (aSAH) is a sudden life-threatening bleeding occurring in the subarachnoid space. It is caused by the rupture of an aneurysm – a weak, bulging spot on the wall of a cerebral artery. Emergency repair (endovascular coiling or microsurgical clipping) is required to stop the hemorrhage.
The bleeding and the release of a vasoconstrictor, endothelin, by the neighboring vascular endothelium, causes many patients to experience vasospasm (constriction of arteries in the brain). This diminishes blood flow to the brain and as a consequence, about one third of patients experience worsening of their neurological condition. Patients with thick and diffuse blood clots are at a significantly higher risk of experiencing cerebral vasospasm. Today, patients with vasospasm are typically treated with hemodynamic therapy, or more invasive neurovascular intervention such as balloon angioplasty or intra-arterial administration of vasodilators.

References

About Idorsia
Idorsia Ltd is reaching out for more - We have more ideas, we see more opportunities and we want to help more patients. In order to achieve this, we will develop Idorsia into one of Europe’s leading biopharmaceutical companies, with a strong scientific core.

Headquartered in Switzerland - a biotech-hub of Europe - Idorsia is specialized in the discovery and development of small molecules, to transform the horizon of therapeutic options. Idorsia has a broad portfolio of innovative drugs in the pipeline, an experienced team, a fully-functional research center, and a strong balance sheet – the ideal constellation to bringing R&D efforts to business success.

Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 700 highly qualified specialists dedicated to realizing our ambitious targets.

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