Idorsia’s P2Y12 receptor antagonist – selatogrel – Phase 2 clinical studies meet their objective

Allschwil, Switzerland – December 18, 2018
Idorsia Ltd (SIX: IDIA) today announced that Phase 2 clinical studies with selatogrel (recommended INN for ACT-246475), Idorsia’s P2Y12 receptor antagonist, in patients with stable coronary artery disease (CAD) and patients with acute myocardial infarction (AMI) have met their pharmacodynamic objectives of significantly inhibiting platelet aggregation.

Subcutaneous administration of selatogrel has demonstrated a rapid onset of action, within 15 minutes, with the height of its effect extending over 4-8 hours, depending on the dose. The predefined extent of platelet aggregation inhibition was seen in at least 89% of the patients in both chronic and acute situations across doses. Selatogrel was safe and well tolerated in both studies and there were no treatment-emergent serious bleeds.

The company is now preparing for the end of Phase 2 meetings with Health Authorities where it will discuss the Phase 3 study. Results of the studies will be shared at upcoming scientific congress and published in scientific literature.

Notes to the editor

Phase 2 study in adults with stable CAD
Idorsia has completed a multicenter, double blind, randomized, placebo-controlled study assessing the pharmacodynamics, pharmacokinetics, tolerability and safety of a single subcutaneous injection of selatogrel in adults with stable coronary artery disease. In this study, 346 patients receiving conventional background oral antiplatelet therapy (e.g. acetylsalicylic acid, P2Y12 receptor antagonists) were randomized to receive either selatogrel 8 mg, 16 mg or placebo. The primary objective of the study was to characterize inhibition of platelet aggregation relative to placebo after a single subcutaneous injection of selatogrel either in the thigh or in the abdomen at 2 different doses in patients with stable CAD.

Phase 2 study in adults with AMI
Idorsia has also completed a multi-center, open-label, randomized, exploratory study to assess the onset of platelet aggregation inhibition after a single subcutaneous injection of selatogrel in adults with acute myocardial infarction. In this study, 48 patients with confirmed diagnosis of AMI and time from onset of symptoms of more than 30 min and less than 6 hours were randomized to receive either selatogrel 8 mg or 16 mg in addition to conventional antithrombotic treatment (e.g., acetylsalicylic acid, oral P2Y12 receptor antagonists, anticoagulants). The primary objective of the study was to assess the inhibition of platelet aggregation 30 minutes after a single subcutaneous injection of selatogrel in patients with AMI.
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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