



Media Release August 23, 2019

Clinical data on Idorsia's pipeline compounds will be presented at the European Society of Cardiology Congress 2019

Allschwil, Switzerland – August 23, 2019

Idorsia Ltd (SIX: IDIA) today announced that data from Phase 2 studies with aprocitentan, a new dual endothelin receptor antagonist, and selatogrel, a highly-selective P2Y₁₂ receptor antagonist, will be shared during the European Society of Cardiology (ESC) Congress 2019 in Paris, France.

Idorsia's aprocitentan

An oral presentation entitled "*Efficacy and safety of various doses of the new dual endothelin receptor antagonist aprocitentan in the treatment of hypertension*", will be part of the "*Drug treatment in hypertension - New insights*" session with a focused discussion with the lead author, Dr Parisa Danaietash from Idorsia, at 09:54 on August 31, 2019. The abstract can be found [online](#).

Idorsia's selatogrel

An oral presentation entitled "*Selatogrel, a novel P2Y₁₂ inhibitor for emergency use, achieves rapid, consistent and sustained platelet inhibition following single-dose subcutaneous administration in stable CAD patients*", will be part of the "*New developments in anti-thrombotic drug therapy*" session with a focused discussion with the lead author, Professor Robert Storey, BM, Professor of Cardiology, University of Sheffield, UK, at 17:15 on September 1, 2019. The abstract can be found [online](#).

A second oral presentation entitled "*Inhibition of platelet aggregation after subcutaneous administration of a single-dose of selatogrel, a novel P2Y₁₂ antagonist, in acute myocardial infarction: A randomised open-label phase 2 study*", will be part of the "*Emerging treatments in acute coronary syndromes*" session with a focused discussion with the lead author, Professor Peter Sinnaeve, MD, Department of Cardiology, University Hospitals Leuven, Faculty of Medicine, University of Leuven, Belgium, at 11:34 on September 3, 2019. The abstract can be found [online](#).

In addition, Idorsia representatives will be present at Stand B320 from 10:00 - 17:00 on Saturday, August 31, until Tuesday, September 3.

Notes to the editor

About aprocitentan

Aprocitentan is an orally active dual endothelin receptor antagonist, which is being investigated for patients whose hypertension is uncontrolled despite the use of three or more antihypertensive drugs.

In June 2018, Idorsia initiated PRECISION, a multi-center, double-blinded, placebo-controlled, randomized, parallel-group, Phase 3 study to demonstrate the antihypertensive effect of aprocitentan when added to standard of care in patients with resistant hypertension. Idorsia, in consultation with regulatory agencies, has designed a single study which will efficiently address both the short-term efficacy of aprocitentan and the durability of its effects in long-term treatment.

Patients with a history of resistant hypertension will undergo a thorough screening and run-in period. This will confirm the diagnosis of resistant hypertension by excluding pseudo or apparent resistant hypertension. During the screening period, the

patient's background antihypertensive therapies will be transitioned to a standardized fixed combination of a calcium channel blocker (amlodipine), an angiotensin receptor blocker (valsartan), and a diuretic (hydrochlorothiazide).

Patients with true resistant hypertension will then be randomized to receive aprocitentan 12.5 mg, 25 mg, or placebo once-daily. The study consists of 3 sequential treatment periods. The first is a double-blind treatment period designed to demonstrate the effect of aprocitentan on blood pressure at Week 4, compared to placebo. Patients then enter a treatment period where they are treated with aprocitentan 25 mg for 32 weeks. This is followed by a double-blind, randomized withdrawal treatment period where patients will remain either on aprocitentan 25 mg or switch to placebo for 12 weeks. The latter treatment period is designed to demonstrate the durability of the blood pressure lowering effect of aprocitentan. Patients will then enter a 30-day safety follow-up period.

From the initial screened patient population, at least 600 patients will be randomized and at least 300 patients are expected to complete the study. The study will be conducted in approximately 100 sites in around 20 countries.

In December 2017, Janssen Biotech, Inc. entered into a collaboration agreement with Idorsia to jointly develop and commercialize aprocitentan and any of its derivative compounds or products. Both parties have joint development rights over aprocitentan. Idorsia will oversee the Phase 3 development and regulatory submission. The costs will be shared equally between both partners. Janssen will oversee the Phase 3 development and submission for any additional indications.

Aprocitentan at ESC-19

Oral presentation:

Efficacy and safety of various doses of the new dual endothelin receptor antagonist aprocitentan in the treatment of hypertension.

Session: Drug treatment in hypertension – new insights, 34.

[P Danaïetash, P Verweij, B Flamion, J Menard, M Bellet; Idorsia Pharmaceuticals Ltd, Allschwil, Switzerland, Clinical Investigation Centre, Inserm /Assistance Publique, Hôpitaux de Paris, Hôpital Européen and Université Paris-Descartes, Paris, France.](#)

Saturday, August 31, 2019, 09:54 - 10:12

About selatogrel

Selatogrel is a highly-selective P2Y₁₂ receptor antagonist developed for acute coronary syndrome.

Two Phase 2 studies in patients with stable coronary artery disease and acute myocardial infarction, respectively, have met their pharmacodynamic objectives of significantly inhibiting platelet aggregation. Subcutaneous administration of selatogrel 8 mg and 16 mg 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. Idorsia is now preparing for the end of Phase 2 meetings with health authorities where it will discuss a Phase 3 study.

Selatogrel at ESC-19

Oral presentation:

Selatogrel, a novel P2Y₁₂ inhibitor for emergency use, achieves rapid, consistent and sustained platelet inhibition following single-dose subcutaneous administration in stable CAD patients.

Session: New Developments in Anti Thrombotic Drug Therapy, 2349.

[Robert Storey, Paul Gurbel, Stefan James, Jurrien ten Berg, Jean-Francois Tanguay, Corine Bernaud, Jean-Marie Frenoux, Abdel Hmissi, Mike Ufer, Pim Van der Harst, Arnoud Van't Hof, George Danqas, Vijay Kunadian, Diana Gorog, Dietmar Trenk, Dominick Anqiollilo.](#)

Sunday, September 1, 2019, 17:15 - 17:32

Oral presentation:

Inhibition of platelet aggregation after subcutaneous administration of a single-dose of selatogrel, a novel P2Y₁₂ antagonist, in acute myocardial infarction: A randomised open-label phase 2 study.

Session: Emerging Treatments in Acute Coronary Syndromes, 5232.

[Peter Sinnaeve, Gregor Fahrni, Dan Schelfaut, Alessandro Spirito, Christian Mueller, Jean-Marie Frenoux, Abdel Hmissi, Corine Bernaud, Mike Ufer, Tiziano Mocetti, Shaul Atar, Marco Valgimigli.](#)

Tuesday, September 3, 2019, 11:34 - 11:48



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 750 highly qualified specialists dedicated to realizing our ambitious targets.

For further information, please contact

Andrew C. Weiss

Senior Vice President, Head of Investor Relations & Corporate Communications

Idorsia Pharmaceuticals Ltd, Hegenheimermattweg 91, CH-4123 Allschwil

+41 (0) 58 844 10 10

www.idorsia.com

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