



## Media Release November 19, 2019

### Idorsia enters into a collaboration with Antares for the development of a novel self-administered drug-device product for selatogrel

- The companies will develop a novel drug-device product combining Idorsia's P2Y<sub>12</sub> receptor antagonist, selatogrel, with the Antares QuickShot<sup>®</sup> auto-injector
- Idorsia is preparing for a Phase 3 study to investigate the efficacy and safety of selatogrel following subcutaneous self-administration for the treatment of a suspected acute myocardial infarction (AMI) in adult patients at risk of recurrent AMI

#### **Allschwil, Switzerland – November 19, 2019**

Idorsia Ltd (SIX: IDIA) today announced that it has entered into a global agreement with Antares Pharma, Inc. (NASDAQ: ATRS) ("Antares") to develop a novel drug-device product combining selatogrel, Idorsia's potent, fast-acting, reversible, and highly selective P2Y<sub>12</sub> receptor antagonist with the Antares subcutaneous QuickShot<sup>®</sup> auto-injector.

With almost 20 years of experience, Antares has a proven track record in developing and commercializing complex drug device products that are tailored to the patient and the therapeutic need.

#### **Jean-Paul Clozel, MD and Chief Executive Officer of Idorsia, commented:**

"For patients suffering an AMI the time from onset of symptoms to first medical contact is critical to preserving muscle and heart function. Our concept of self-administration of a potent, fast-acting P2Y<sub>12</sub> receptor antagonist at onset of symptoms could have significant potential. This potential can only be unlocked when our compound is brought together with the right device. Hence finding a safe and reliable device which is easy for patients to use under stressful conditions was a key part for the further development. I'm confident that with Antares we have found the right partner to deliver on this mission."

Selatogrel is presented as a single-dose, ready-to-use, disposable drug-device product, which consists of a self-administration QuickShot<sup>®</sup> auto-injector containing a drug prefilled syringe. The product is going to be tested through usability and reliability studies tailored for emergency use to ensure safe and effective use can be demonstrated ahead of the Phase 3 study.

#### **Jean-Paul Clozel, MD and Chief Executive Officer of Idorsia, added:**

"The team at Idorsia is also preparing a comprehensive program to train patients on when to inject and instruct them on how to self-administer treatment. It is a challenging but incredibly exciting project, and as a cardiologist, I know how important early treatment at the very onset of symptoms of an AMI is. Based on our current plans, the usability and reliability studies, and ongoing discussions with health authorities, I hope that we can initiate the Phase 3 in the first half of 2021."

#### **Robert F. Apple, President and Chief Executive Officer of Antares, said:**

"Today, we are extremely pleased to announce a new and important global development agreement with Idorsia Pharmaceuticals, one of Europe's premier biopharmaceutical companies. Idorsia is developing a novel approach to treating patients with a suspected AMI on an emergency basis using



selatogrel with our proven QuickShot device. Idorsia hopes to improve upon outcomes for those patients experiencing a recurrent heart attack by providing a rapid and sustained platelet inhibition thus potentially providing for early treatment of AMI.”

#### **Terms of the collaboration**

Idorsia will pay for the development of the drug device product and will be responsible for applying for and obtaining global regulatory approvals for the product.

The parties intend to enter into a separate commercial license and supply agreement pursuant to which Antares will provide fully assembled and labelled product to Idorsia at cost plus margin. Idorsia will then be responsible for global commercialization of the product, pending regulatory approval.

Antares will be entitled to receive royalties on net sales of the commercial product.

#### **Robert F. Apple, President and Chief Executive Officer of Antares, concluded:**

“This is one of the most exciting and innovative partner product opportunities we have ever worked on in the Company’s history. The development agreement between Antares and Idorsia further expands our portfolio of pipeline partnered products and represents our first opportunity to develop a combination product utilizing a partner’s compound. We believe our track record of drug device combination product approvals is impressive, speaks to the reliability of our device platforms and we believe is why Idorsia chose to work with Antares on this exciting product. We look forward to working closely with Idorsia throughout the development phase of this novel product and assisting them in pursuing FDA drug device and global regulatory approval assuming successful completion of their Phase 3 study.”

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### **Notes to the editor**

#### **About AMI**

An AMI, or heart attack, is a life-threatening condition that occurs when blood flow to the heart muscle is suddenly decreased or completely cut off. It is usually caused by a blood clot or blockage in one or more of the coronary vessels supplying blood to the heart muscle. An AMI requires immediate treatment and medical attention, as any delay in intervention can result in irreversible damage to the heart muscle. The American Heart Association estimates that each year more than 600,000 persons living in the US will suffer their first heart attack and around 200,000 will suffer a recurring heart attack.

AMI is associated with a 30% mortality rate and about half of these deaths occur prior to arrival at the hospital. As a result, early action is crucial for survival, however there are no treatment options available for the critical time from onset of AMI symptoms to first medical contact. The need for an early intervention has been highlighted by the guidelines of the European Society of Cardiology and the American College of Cardiology / American Heart Association, which identified the prehospital phase as the most critical and reiterated that efforts must be made to reduce the delay for treatment initiation to reduce death.

#### **About selatogrel**

Idorsia is developing selatogrel, a potent, fast-acting, reversible, and highly-selective P2Y12 receptor antagonist, for single subcutaneous self-administration for the treatment of a suspected AMI in patients with a history of AMI.

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. Selatogrel was safe and well tolerated in both studies and there were no treatment-emergent serious bleeds.

In consultation with health authorities, Idorsia is preparing a large, international, multi-center, Phase 3 study to investigate the efficacy and safety of subcutaneous self-administration of selatogrel for the treatment of a suspected AMI in patients with an history of AMI. Participating patients will be trained on when to inject and instructed on how to self-administer treatment.



Both studies were presented at ESC 2019:

"Selatogrel, a novel P2Y12 inhibitor for emergency use, achieves rapid, consistent and sustained platelet inhibition following single-dose subcutaneous administration in stable CAD patients" Professor Robert Storey, BM, Professor of Cardiology, University of Sheffield, UK. The abstract can be found [online](#).

"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", Professor Peter Sinnaeve, MD, Department of Cardiology, University Hospitals Leuven, Faculty of Medicine, University of Leuven, Belgium. The abstract can be found [online](#).

A manuscript for the study of selatogrel in stable CAD patients is also now available:

Storey RF, et al, Pharmacodynamics, pharmacokinetics, and safety of single-dose subcutaneous administration of selatogrel, a novel P2Y12 receptor antagonist, in patients with chronic coronary syndromes. European Heart Journal (2019) 0, 1–9  
doi:10.1093/eurheartj/ehz807

#### **About Antares Pharma Inc.**

Antares Pharma, Inc. is a combination drug device company focused primarily on the development and commercialization of self-administered parenteral pharmaceutical products using advanced drug delivery auto injector technology. The Company has a portfolio of proprietary and partnered commercial products with several product candidates in various stages of development, as well as significant strategic alliances with industry leading pharmaceutical companies including Teva Pharmaceutical Industries, Ltd. (Teva), AMAG Pharmaceuticals, Inc. and Pfizer Inc. (Pfizer). Antares Pharma's proprietary products include XYOSTED® (testosterone enanthate) injection, OTREXUP® (methotrexate) injection for subcutaneous use and Sumatriptan Injection USP, which is distributed by Teva.

Antares Pharma, Inc. (NASDAQ: ATRS) is headquartered in Ewing, New Jersey, US and listed on NASDAQ.  
[www.antareshpharma.com](http://www.antareshpharma.com).

#### **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.

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