



## **ANTARES PHARMA ENTERS INTO A GLOBAL DEVELOPMENT AGREEMENT WITH IDORSIA PHARMACEUTICALS LTD.**

### ***Novel Drug Device Combination Product To Be Developed For The Treatment Of Suspected Acute Myocardial Infarction***

**EWING, NJ, November 19, 2019** -- Antares Pharma, Inc. (NASDAQ: ATRS) ("Antares") today announced that it has entered into a global agreement with Idorsia Pharmaceuticals Ltd. ("Idorsia") (SIX: IDIA) to develop a novel, drug-device product combining selatogrel, Idorsia's potent, fast-acting and highly selective P2Y<sub>12</sub> receptor antagonist under development, with the Antares subcutaneous QuickShot<sup>®</sup> auto injector. Selatogrel, a new chemical entity (NCE), is being developed for the treatment of a suspected acute myocardial infarction (AMI) in adult patients with a history of AMI. Idorsia's Phase 2 clinical data demonstrated that subcutaneous administration of selatogrel resulted in a potent and rapid platelet inhibition effect in patients with a history of coronary artery disease and AMI. According to Idorsia, the product was safe and well tolerated. Idorsia is now preparing for a clinical bridging study to be followed by a global Phase 3 study of a self-administered QuickShot<sup>®</sup> auto injector containing selatogrel for the pre-hospital treatment of a suspected acute myocardial infarction.

"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 a new chemical entity, 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," said Robert F. Apple, President and Chief Executive Officer of Antares. "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 NCE. 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."

Idorsia will pay for the development of the combination 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 FDA or foreign approval. Antares will be entitled to receive royalties on net sales of the commercial product.

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." He 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."

## **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. Idorsia has previously announced that 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. According to the studies, 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. Selatogrel has not been approved by the FDA in the United States or any foreign country.

Both studies were presented at the European Society of Cardiology 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 Acute Myocardial Infarction**

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 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.

## **About Antares Pharma**

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.

## **SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

**This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to: successful development including the timing and results of the clinical bridging and Phase 3 clinical trial of the drug device combination product for Selatogrel with Idorsia Pharmaceuticals and FDA and global regulatory approvals and future revenue from the same; market acceptance, adequate reimbursement coverage and commercial success of XYOSTED™ and future revenue from the same; market acceptance of Teva's generic epinephrine auto-injector product and future revenue from the same; our expectations regarding whether the FDA will pursue withdrawal of approval for AMAG Pharmaceuticals Inc.'s Makena® subcutaneous auto injector following the recent FDA advisory committee meeting and future prescriptions, market acceptance and revenue from Makena® subcutaneous auto injector; Teva's ability to successfully commercialize VIBEX® Sumatriptan Injection USP and the amount of revenue from the same; continued growth of prescriptions and sales of OTREXUP®; the timing and results of the Company's or its partners' research projects or clinical trials of product candidates in development; actions by the FDA or other regulatory agencies with respect to the Company's products or product candidates of its partners; continued growth in product, development, licensing and royalty revenue; achievement of the 2019 revised revenue guidance; the Company's ability to meet loan extension and interest only payment milestones and the ability to repay the debt obligation to Hercules Capital; the Company's ability to obtain financial and other resources for its research, development, clinical, and commercial activities and other statements regarding matters that are not historical facts, and involve predictions. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance, achievements or prospects to be materially different from any**

future results, performance, achievements or prospects expressed in or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terminology such as "may", "will", "should", "would", "expect", "intend", "plan", "anticipate", "believe", "estimate", "predict", "potential", "seem", "seek", "future", "continue", or "appear" or the negative of these terms or similar expressions, although not all forward-looking statements contain these identifying words. Additional information concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the "Risk Factors" section of the Company's Annual Report on Form 10-K, and in the Company's other periodic reports and filings with the Securities and Exchange Commission. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to the Company on the date hereof, and the Company undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this press release, except as required by law.

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