Hyloris Acquires Breakthrough, Patented Technology to Develop and Market Aspirin IV in the U.S. in Acute Coronary Syndrome

Potential to revolutionise the current treatment paradigm and become the cornerstone therapy for patients with suspected acute coronary syndrome

Enables accelerated development of HY-073 (IV acetylsalicylic acid), bringing the anticipated FDA submission date forward to end 2023

Initially targeting a total addressable patient population of ~2 million in the U.S.

Liège, Belgium – 13 October 2021 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that it has entered into an exclusive, worldwide licensing agreement with Rhoshan Pharmaceuticals Inc. ("Rhoshan"), to develop, manufacture and commercialise intravenous acetylsalicylic acid (previously known as Hyloris' HY-073) for the treatment of patients with suspected acute coronary syndromes (ACS). Acetylsalicylic acid IV is currently not available in the U.S. and Hyloris anticipates commercialising the product in the U.S. with its own future sales force targeting cardiologists in the hospital setting.

Coronary heart disease (CHD) is a common term for the build-up of plaque in the heart's arteries, and is the leading cause of mortality in the U.S.[1] CHD can lead to ACS, life-threatening conditions that account for 50% of all cardiovascular disease-related deaths, including acute myocardial infarction (heart attack), unstable angina (chest pain that may signal an impending heart attack) or sudden cardiac death. About 2 million patients with acute myocardial infarction and unstable angina are admitted to the hospital each year in the U.S.[2]

"Rhoshan Pharmaceuticals believes that the clinical impact of injectable Aspirin could be tremendous, starting in the cardiovascular setting. Every minute is critical when treating a suspected myocardial infarction, and this product has the potential to save precious time in this hyperacute setting," **said Hitha Palepu, Chief Executive Officer of Rhoshan Pharmaceuticals.** *"Our partnership with Hyloris aligns our development expertise with their experience in commercialisation, and we look forward to the collective impact we can have on making healthcare better, together."*

Stijn Van Rompay, Chief Executive Officer of Hyloris, added: "*Developing an IV formulation of acetylsalicylic acid, the active ingredient of Aspirin, is a challenge due to its inherent chemical instability and poor solubility. We are very pleased to join forces with the team at Rhoshan and implement their breakthrough, proven IV formulation technology to accelerate the development of HY-073, thereby shortening overall timelines. We expect to start the pivotal study early 2022, with the submission of the regulatory dossier to the FDA now already anticipated towards end 2023*."

Under the terms of the agreement with Rhoshan, Hyloris acquires an exclusive worldwide license to all intellectual property rights, knowhow, and technical proprietary information in relation to the IV formulation technology (U.S. patent granted on 31 March 2021) to develop intravenous acetylsalicylic acid in multiple indications. Hyloris will be responsible for the manufacturing and commercialisation of the product, whereas Rhoshan will continue product development and regulatory affairs activities, and will bear the NDA submission costs. Rhoshan will receive an upfront payment of $750,000; and is eligible to receive $1.25 million development and regulatory milestones; commercial-based

[1] Centers for Disease Control and Prevention; American Heart Association, Heart Disease & Stroke Statistics (2019)
[2] Premier Healthcare Database; Malik et al, Annals of Translational Medicine, 2018

milestones, as well as a share of net profit. Hyloris will provide maximum $7.5 million in R&D funding up to, and including, regulatory approval.

About coronary heart disease (CHD), acute coronary syndrome (ACS) and Aspirin IV U.S.

CHD occurs when the heart's blood supply is blocked due to the build-up of fatty substances in the arteries around the heart. This can lead to blood clots that restrict blood flow and cause ACS, including unstable angina, acute myocardial infarction, and even cardiac arrest. Patients with symptoms of ACS are admitted to the hospital emergency room and oral aspirin therapy (162 to 325 mg per day) should start as soon as possible and be continued to delay and prevent further blood clotting.[3] Each minute after a heart attack, more heart tissue deteriorates or dies, so restoring blood flow quickly and effectively helps prevent heart damage. However, it takes on average 1-2 hours for oral aspirin to reach peak effectivity and there can be material variabilities which can result in significant delay, or even lack of, effect in subgroups of patients. Moreover, many patients with ACS symptoms are not eligible for oral administration due to their acute condition.

Aspirin IV U.S. is a first-in-class IV formulation of acetylsalicylic acid that could significantly improve treatment outcomes of patients with ACS based on its potential life-saving benefits: i) a fast and more pronounced onset of activity (5 minutes to reach maximum peak concentrations) and a sustained effect over a few hours; ii) less intra- and interindividual metabolisation variabilities as it is given intravenously and thus has 100% bioavailability.

About Rhoshan Pharmaceuticals

Rhoshan Pharmaceuticals, Inc is a specialty biopharmaceutical company focused on bringing the first injectable aspirin to US market. The company was founded by Nagesh Palepu, a highly experienced formulator in the enhanced formulation space. He has helped develop 3 505(b)(2) products in the past 17 years (and over 50 products in his career) and is the inventor of over 150 patents worldwide. Rhoshan Pharmaceuticals' team brings centuries of experience in formulation, CM&C, clinical development, and regulatory affairs. Rhoshan Pharmaceuticals is headquartered in Chadds Ford, Pennsylvania. For more information, visit www.rhopharma.com.

About Hyloris Pharmaceuticals

Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimising existing medications to address important healthcare needs and deliver relevant improvements for patients, healthcare professionals and payors. Hyloris has built a broad, patented portfolio of 13 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Outside of its core strategic focus, the Company also has 3 high barrier generic products in development and registration phase. Two products are currently in initial phases of commercialisation with partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. The Company's development strategy primarily focuses on the FDA's 505(b)2 regulatory pathway, which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This pathway can reduce the clinical burden required to bring a product to market, and significantly shorten the development timelines and reduce costs and risks. Hyloris is based in Liège, Belgium. For more information, visit www.hyloris.com and follow-us on LinkedIn.

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[3] AHA Guidelines; Circulation 2013

Disclaimer and forward-looking statements

Hyloris means “high yield, lower risk”, which relates to the 505(b)(2) regulatory pathway for product approval on which the Issuer focuses, but in no way relates or applies to an investment in the Shares.

Certain statements in this press release are “forward-looking statements.” These forward-looking statements can be identified using forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. These statements relate to future events or the Company’s future financial performance and involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Company’s control, that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by any forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.