Press Release
Regulated Information – Inside information

Hyloris Announces Partnership with Rosemont Pharmaceuticals for Atomoxetine Oral Solution in the U.S.

Exclusive License and Supply Agreement signed with Rosemont Pharmaceuticals for the U.S.

Liège, Belgium – 29 December 2025 – 08.00 PM CET - Regulated Information - Inside information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), the specialty biopharma company committed to addressing unmet medical needs through reinventing and optimizing existing medications, today announces the signing of an exclusive out-licensing and supply agreement for its proprietary Atomoxetine Oral Solution with Rosemont Pharmaceuticals ("Rosemont").

Under the agreement, Hyloris will be responsible for the product approval and supply related activities while Rosemont will focus on commercialization in the U.S. Hyloris will receive milestone payments and royalties from product sales.

Atomoxetine Oral Solution is designed to offer a precise and titratable alternative to existing oral atomoxetine capsules, supported by positive results from a pivotal BA/BE study[1] completed in July 2025. The formulation has been specifically developed for children, adolescents, and adults with attention deficit hyperactivity disorder (ADHD) who have difficulty swallowing solid oral dosage forms or who require individualized dose titration.

Stijn van Rompay, Chief Executive Officer of Hyloris, commented: "*We are excited to partner one more product with Rosemont, as this collaboration leverages both companies' strengths and positions us well for success in the U.S. market. We believe strongly in the potential of Atomoxetine Oral Solution as a much-needed treatment option for people with ADHD. By providing a precise and easy-to-administer liquid formulation, we hope to improve access and adherence to a therapy for patients who have long faced limited alternatives. This is especially important for those who have difficulty swallowing solid dosage forms or who need personalized dosing.*"

About atomoxetine and Atomoxetine Oral Solution

Atomoxetine is a non-stimulant prescription-only medication used to treat symptoms of attention deficit hyperactivity disorder (ADHD) in both adults and children aged six years and older. It works by selectively inhibiting the reuptake of norepinephrine, a neurotransmitter, helping to improve focus, attention, and impulse control in individuals with ADHD. In 2023 approximately 3.4 million prescriptions for atomoxetine were filled for over 750,000 patients in the U.S.[2.] In 2024, over 197 million capsules were sold, reflecting a 16% growth compared to the previous year[3].

Despite its widespread use, administering atomoxetine - especially to children - can be challenging. The drug requires dose titration, and the commercially available capsule formulation can potentially

1 A bioavailability/bioequivalence (BA/BE) study is a clinical study designed to demonstrate that a drug formulation delivers the active ingredient to the body at the same rate and extent as a reference product

2 https://clincalc.com/DrugStats/Drugs/Atomoxetine

3 IQVIA

be difficult to swallow, which may present a risk of choking or inhalation. Currently, liquid formulations of atomoxetine, which are common internationally, are not available in the U.S. market.

Atomoxetine Oral Solution, developed by Hyloris, is an innovative, patent-pending liquid formulation designed to address these challenges. It offers a precise, titratable, and stable alternative to capsules, facilitating accurate dosing and titration. This formulation improves convenience and adherence, particularly among children and adults with dysphagia. Additionally, to make the solution more palatable and child-friendly, the formulation incorporates an innovative taste-masking component.

About attention deficit hyperactivity disorder (ADHD)

ADHD is a chronic neurodevelopmental disorder that begins in childhood and often persists into adulthood. It is characterized by impaired attention, motor hyperactivity, and impulsiveness. Affecting slightly over 10% of children aged 4 to 17 in the U.S., ADHD is among the most common neurobehavioral disorders in this age group.[4]

Children and adolescents with ADHD face significant challenges, including impulsive behavior and slower information processing, which can result in poorer academic performance and a higher risk of dropping out. Symptoms persist into adulthood for 60% to 80% of those affected, with an estimated 4.0% to 4.5% of U.S. adults living with ADHD[5].

About Hyloris Pharmaceuticals

Hyloris is the specialty biopharma company focused on innovating, reinventing, and optimizing existing medications to address important healthcare needs and deliver relevant improvements for patients, healthcare professionals and payors.

The Company's development strategy primarily focuses on leveraging established regulatory pathways, such as the FDA's 505(b)(2) pathway in the U.S or equivalent regulatory frameworks in other regions which are specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This approach can reduce the clinical burden required for market entry, and significantly shorten the development timelines, leading to reduced costs and risks.

Hyloris has built a broad development portfolio of 27 products, including 23 reformulated and/or repurposed value-added medicines that have the potential to offer significant advantages over existing alternatives. Two products are currently in early phases of commercialization in collaboration with commercial partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. In addition to its core strategic focus, the Company has 2 high barrier generic products approved in the U.S. and 1 high barrier generic product in development. Hyloris continuously evaluates additional product opportunities to drive future growth.

Hyloris is based in Liège, Belgium and is listed on Euronext Brussels (EBR: HYL). For more information, visit www.hyloris.com and follow-us on LinkedIn.

About Rosemont Pharmaceuticals

Rosemont has over 50 years of expertise in the development, manufacture and distribution of oral liquid medicines. Since the release of its first liquid medicine in 1974, Rosemont has continued conducting research, developing, and bringing new products to market advocating support for vulnerable patients with swallowing difficulties. As of 2024, Rosemont has a portfolio of over 130 oral liquid medicines across a range of therapeutic areas including over 100 licensed products in 27 international markets. In July 2024 Rosemont announced the acquisition of Sabal Therapeutics, a US based pharmaceutical company, specialized in liquid medicines, thereby expanding their footprint into the U.S. Learn more at www.rosemontpharma.com

[4] Li Y, Yan X, Li Q, et al. Prevalence and Trends in Diagnosed ADHD Among US Children and Adolescents, 2017-2022. *JAMA Netw Open.* 2023;6(10):e2336872. doi:10.1001/jamanetworkopen.2023.36872
[5] Sharma and Couture, Ann Pharmacother. 2014

For more information, contact Hyloris Pharmaceuticals:

Ann De Jaeger, CLO, legal representative of Impact WITH Empathy BV
Ann.dejaeger@hyloris.com
+32 (0)475 20 13 44 - +32 (0)4 346 02 07

Stijn Van Rompay, CEO, legal representative of SVR Management BV
stijn.vanrompay@hyloris.com
+32 (0)4 346 02 07

Christophe Maréchal, CFO, legal representative of CMM&C srl
Christophe.Marechal@hyloris.com
+32 (0)4 346 02 07

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 Company 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.

This press release contains information about a product under development and is not intended as a promotional statement. The product mentioned is subject to regulatory approval and is not currently available for sale. Please consult licensed medical professionals for healthcare decisions.