Hyloris Announces Out-Licensing of Atomoxetine Oral Liquid in Canada

- Territorial expansion for a product candidate previously exclusively targeting the U.S.
- Kye Pharmaceuticals to register and commercialize in Canada

Liège, Belgium – 24 October 2023 – 7AM CET – Non-regulated information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces it has out-licensed its product candidate atomoxetine oral liquid for the treatment of attention deficit hyperactivity disorder (ADHD) in Canada to Kye Pharmaceuticals.

ADHD is one of the most common neurobehavioral disorders, affecting 4-6% of adults and 5-7% of children in Canada, or approximately 1,8 million Canadians[1]. It is a chronic condition for most patients, with approximately 60 to 80% of the symptoms of ADHD persisting into adulthood[2].

Global prevalence of ADHD has increased significantly in recent years[3], leading to an increased usage of ADHD therapies such as the well-established medication atomoxetine. In 2022, the Canadian market amounted to 17 million capsules (CAGR of 7,4% in the period 2020-2022)[4] of atomoxetine.

Atomoxetine is currently not available as an oral liquid formulation in Canada. Considering the added value, significant market share penetration was often observed in countries when an oral liquid became available in this drug category[5].

Kye Pharmaceuticals is targeting a regulatory submission in 2024, and will be the exclusive partner for commercialization in Canada. The territorial expansion for atomoxetine oral liquid should not result in additional product-related investments for Hyloris.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"We are proudly partnering with this local champion focused on commercializing therapies within pediatrics and neurosciences. Partnering atomoxetine oral liquid outside of the U.S. underlines our capability to bring innovative treatments to patients on a global scale, and unlock the hidden value in our existing pipeline of reformulated and repurposed product candidates."*

[1] https://caddac.ca/about-adhd/
[2] https://journals.sagepub.com/doi/10.1177/1060028013510699
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9616454/
[4] IQVIA
[5] IQVIA

John McKendry, President of Kye, commented: *"Many Canadians with ADHD are unable to take solid tablets as prescribed, and alternative formulations which have been available internationally are not readily available in the Canadian market. This partnership expands our growing portfolio of innovative ADHD treatments and will ensure Canadian patients have access to a liquid formulation of atomoxetine, a well-established non-stimulant medication."*

Under the terms of the agreement, Hyloris will be eligible to receive attractive sales-related milestone payments (totalling up to USD 7,5 million), and a substantial share of the revenue generated in Canada.

About Attention Deficit Hyperactivity Disorder (ADHD)

ADHD is a chronic mental childhood-onset disorder characterized by developmentally inappropriate and impaired inattention, motor hyperactivity, and impulsivity, with difficulties often continuing into adulthood. Children and adolescents suffering from ADHD experience challenging key formative years. Because of impulsive behaviour and slower rates of processing information, they perform poorly on standardized tests, score lower grades and are more likely to drop out of school.

About atomoxetine oral liquid

Atomoxetine is a non-stimulant prescription medication used to treat ADHD symptoms in adults and children over the age of 6. For patients up to 70kg body weight, administration of atomoxetine is initiated as a total daily dose of 0.5 mg/kg/day up to a target total daily dose of approximately 1.2 mg/kg either as a single daily dose or as evenly divided doses.

An easy-to-swallow oral liquid formulation of atomoxetine could facilitate accurate dosing through titration. In addition, it could offer improved patient compliance and convenience, particularly in patients with dysphagia (who have difficulty swallowing capsules).

Due to the pediatric use for this product candidate, Hyloris deployed an innovative taste masking strategy targeting a preferred taste for young patients.

For the U.S. market, a pivotal clinical study is in preparation as previously announced.

About Hyloris

Hyloris is a 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. Hyloris has built a broad, patented portfolio of 16 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.

Two products are currently in initial phases of commercialization 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.

About Kye Pharmaceuticals

Kye Pharmaceuticals is a private company headquartered in Canada focused on bringing medications to the Canadian market which fulfill clinically significant unmet needs. Kye continues to license, register, and commercialize innovative prescription medicines. Kye was founded on an entrepreneurial spirit, applying the team's diverse strengths to a growing portfolio, and delivering value to its partners, healthcare professionals, and most importantly, patients across Canada. For more information please visit www.kyepharma.com.

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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.