Press Release
Regulated Information – Inside information

Hyloris Announces Positive Clinical Study Results for Atomoxetine Oral Solution

- Clinical Study Demonstrates Comparable Relative Bioavailability to Strattera® Capsules as Sold in the U.S.
- New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) Under Preparation

Liège, Belgium – 17 July 2025 – 07:00 AM CET – Regulated Information – Inside information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announced positive results from a pivotal clinical study of its proprietary Atomoxetine Oral Solution.

This patent-pending liquid formulation of atomoxetine is designed to provide a precise and titratable alternative to Strattera® (oral atomoxetine capsules), and has been specifically developed for children, adolescents, and adults with attention deficit hyperactivity disorder (ADHD) who have difficulty swallowing solid oral dosage forms or require individualized dose titration.

The study demonstrated that Atomoxetine Oral Solution has comparable relative bioavailability[1] under fasted conditions to Strattera® capsules as sold in the U.S. Additionally, the bioavailability of atomoxetine was not affected by food intake when administered as an oral solution. These results support the continued preparation of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA).

Stijn van Rompay and Thomas Jacobsen, co-Chief Executive Officers of Hyloris, commented: *"We are excited about 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 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. Other ADHD treatments with liquid formulations have typically captured a notable share of the oral market. This advancement reinforces our commitment to addressing unmet medical needs, and we look forward to progressing towards FDA approval to bring this important option to those who need it most."*

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 2022, approximately 1.8 million prescriptions for atomoxetine were filled for around 0.5 million patients in the U.S.[2], and in 2024, over 197 million capsules were sold, reflecting a 16% growth compared to the previous year[3].

[1] Relative bioavailability compares how much of a drug is absorbed into the bloodstream from one formulation versus another, such as a liquid versus a capsule

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

[3] IQVIA

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 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 Pharmaceuticals, is a novel, 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 the pivotal study of Atomoxetine Oral Solution

The primary objective of the pivotal study was to assess the relative bioavailability of Atomoxetine Oral Solution under fasting conditions in healthy volunteers as well as to assess the effect of food on the bioavailability. The secondary objective was to evaluate its safety and tolerability under both fasting and fed conditions. Results demonstrate comparable relative bioavailability to Strattera® capsules under fasted conditions and confirmed that the Oral Solution was safe and well tolerated.

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 impulsivity. Affecting 2% to 18% of children aged 6 to 17 in the U.S., ADHD is among the most common neurobehavioral disorders in this age group.

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[4].

About Hyloris Pharmaceuticals

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.

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 26 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.

[4] Sharma and Couture, Ann Pharmacother. 2014

Hyloris is based in Liège, Belgium. For more information, visit www.hyloris.com and follow-us on LinkedIn.

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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.

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