Hyloris Announces Further Positive Study Results and Strengthens Global Reach for Valacyclovir Oral Suspension with Expanded Rights

- Clinical Study Demonstrates Comparable Relative Bioavailability to Valacyclovir Tablets under Fasted Conditions
- Global Expansion Through Exclusive Commercial Rights Secured in Additional Markets
- New Drug Application (NDA) Expected to be Submitted to the U.S. Food & Drug Administration (FDA) Before the End of 2024

Liège, Belgium – 12 August 2024 – 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 announces positive results from a pivotal clinical study evaluating its proprietary Valacyclovir Oral Suspension. The additional pivotal clinical study demonstrates comparable relative bioavailability to Valtrex® tablets, as sold in the U.S, under fasted conditions. These results further strengthen the clinical data package and support the ongoing preparation of an NDA for submission to the U.S. Food & Drug Administration (FDA) targeted before the end of 2024.

Hyloris has furthermore significantly expanded its global commercial reach beyond its initial U.S. focus by securing exclusive rights for Valacyclovir Oral Suspension in a wide range of new territories including major European markets (such as the Nordics, Germany, France, Italy and the UK), Canada, Mexico, Australia, China, South Korea and the GCC countries. A clinical study is set to commence before the end of 2024, with the aim of submitting the first regulatory application for these new markets in 2025.

Thomas Jacobsen and Stijn Van Rompay, co-Chief Executive Officers of Hyloris, commented: “We are delighted by the successful results of this Valacyclovir Oral Suspension clinical study. The expanded commercial rights granted will empower us to deliver this innovative formulation to many more patients globally. Our novel suspension offers distinct advantages, including improved dosing accuracy, enhanced stability over compounded products and potentially leading to increased patient compliance."

About the pivotal study

The primary objective was to compare the proprietary Valacyclovir Oral Suspension (200 mg/mL) with Valtrex® tablets (1000 mg) in its solid form. In this study, the relative bioavailability of valacyclovir and

its converted form, acyclovir1 was measured after administration in healthy volunteers under fasted conditions[2].

In late 2023, the Company announced positive data of it's first pivotal clinical trial comparing the relative bioavailability of Hyloris' proprietary 200 mg/mL Valacyclovir Oral Suspension to extemporaneously[3] prepared oral suspension of Valtrex® tablets (50 mg/mL)

About Valacyclovir

Valacyclovir, currently commercialized as a solid oral in the U.S, is used to treat herpes virus infections, including herpes labialis (also known as cold sores), herpes zoster (also known as shingles), and herpes simplex (also known as genital herpes) in adults. For pediatric patients, the drug was approved for cold sores (herpes labialis) and chickenpox. Valacyclovir is available by prescription only, and the dosage and duration of treatment depend on the specific condition being treated and the individual patient's medical history.

Data suggests 5,5 million prescriptions[4] to over 2,4 million patients in the U.S. were filled in 2020. In 2023 more than 577 million tablets were sold in the U.S, growing at a CAGR[5] of 3,6%. Additionally, in the newly added territories, approximately 400 million tablets were sold, growing at a CAGR of 5,8%[6].

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, patented portfolio of 18 reformulated and 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 1 approved high barrier generic product launched in the U.S. and 2 high barrier generic products in development.

[1] Valacyclovir is nearly completely converted to acyclovir by first-pass metabolism
[2] The abstinence of food and drinks except water for a period of time prior to dosing
[3] An extemporaneous preparation is a drug or mixture of drugs prepared or compounded in a pharmacy according to a prescribers instruction.
[4] Valacyclovir - Drug Usage Statistics, ClinCalc DrugStats Database.
[5] Compounded annual growth rate over 3 years
[6] Source: IQVIA.

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.