Press Release
Regulated Information – Inside information

Hyloris Announces Positive Study Results for Valacyclovir Oral Suspension for European Markets

- Clinical Study Demonstrates Comparable Relative Bioavailability to Valacyclovir Tablets as Sold in Europe
- Regulatory Submissions for Selected European Markets are Planned for the First Half of 2025

Liège, Belgium – 29 December 2024 – 10.00 pm 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 reports positive results from a pivotal clinical study of its proprietary Valacyclovir Oral Suspension. The study confirms that the product demonstrates comparable relative bioavailability to Valtrex® tablets, as marketed in Europe, under fasted conditions.

These results support the planned regulatory submissions to selected regulatory agencies outside the U.S., which are scheduled as from the first half of 2025.

Hyloris holds exclusive rights to its Valacyclovir Oral Suspension across a broad range of territories, beyond its initial U.S. focus, to include major European markets (such as the Nordics, Germany, France, Italy and the UK), Canada, Mexico, Australia, China, South Korea and the GCC countries.

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 as commercialized in Europe. In this study, the relative bioavailability of valacyclovir and its converted form, acyclovir[1] was measured after administration in healthy volunteers under fasted conditions[2].

Earlier, the Company announced positive data of two pivotal clinical trials 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) and to Valtrex® tablets, as sold in the U.S.

About Valacyclovir

Valacyclovir, currently commercialized as a solid oral, is used to treat herpes virus infections, including herpes labialis (also known as cold sores), herpes zoster (also known as shingles). 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.

[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.

In the targeted territories outside the U.S., approximately 400 million tablets were sold, with a compound annual growth rate (CAGR) of 5,8%.[4] These markets collectively represent an annual sales value of USD 249 million.

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 19 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.

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

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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

[4] Source: IQVIA.

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.

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.

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.