Hyloris Announces Positive Clinical Study Results for Valacyclovir Oral Suspension (HY-029)

- Valacyclovir is an Antiviral Medication that is Commonly Used to Treat Infections Caused by Herpes Viruses
- Clinical Study Demonstrates Comparable Relative Bioavailability to Valaciclovir Tablets under fasted conditions
- NDA submission[1] (NDA) to the U.S. Food & Drug Administration (FDA) expected in 2024

Liège, Belgium – December, 26 2023 – 6PM 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 for its proprietary Valacyclovir Oral Suspension. It allows for further preparation of a NDA[1] for submission to the FDA expected in 2024.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"We are one step closer to bringing a new and improved mode of administration for this well-known molecule, prescribed more than 5 million times annually in the U.S[2]. Multiple benefits are to be expected from our novel formulation which addresses potential dosing inaccuracies associated with crushing tablets, aiming to enhance stability and storability, ultimately contributing to increased patient compliance and improved quality of life."*

About the pivotal study

The primary objective was to compare the proprietary Valacyclovir Oral Suspension (200 mg/mL) with Valtrex® tablets (50 mg/mL) prepared as an extemporaneous suspension[3]. The relative bioavailability of valacyclovir and acyclovir[4] was measured after administration under fasted conditions[5]. In addition, the

[1] After completion of the required stability and clinical activities.
[2] Valacyclovir - Drug Usage Statistics, ClinCalc DrugStats Database.
[3] An extemporaneous preparation (compound) is a drug or mixture of drugs prepared or compounded in a pharmacy according to the order of a prescriber.
[4] Valacyclovir is nearly completely converted to acyclovir by first-pass metabolism.
[5] The abstinence of food and drinks except water for a period of time prior to dosing.

effect of food on the bioavailability of acyclovir after administration of proprietary Valacyclovir Oral Suspension (200 mg/mL) was assessed.

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.

Estimates indicate 5,5 million prescriptions[6] to over 2,4 million patients in the U.S. in 2020. In 2022 more than 560 million tablets were sold, growing at a CAGR of 5%[7].

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 17 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 1 approved high barrier generics product launched in the U.S. and 2 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

[6] Valacyclovir - Drug Usage Statistics, ClinCalc DrugStats Database.
[7] Source: IQVIA.

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.

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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.