Press Release
Regulated Information – Inside information

Hyloris Announces FDA Acceptance of New Drug Application (NDA) for Valacyclovir Oral Liquid

PDUFA Target Action Date Set at October 12, 2025

Liège, Belgium – 25 February 2025 – 07.15 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 the U.S. FDA has accepted for review the New Drug Application (NDA) for its proprietary Valacyclovir oral suspension. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 12, 2025

The NDA submission is supported by robust data from two pivotal clinical trials that demonstrated comparable relative bioavailability[1] of Hyloris' proprietary Valacyclovir oral suspension to Valtrex® tablets.

"We are delighted with the FDA's acceptance of this NDA for Valacyclovir oral suspension as it marks a significant milestone in our mission to address unmet medical needs" said Stijn Van Rompay and Thomas Jacobsen, Co-CEOs. "This milestone brings us closer to providing patients with a more convenient form of an established therapy, which could lead to better treatment adherence and improved outcomes."

About Valacyclovir Oral Suspension

Valacyclovir, which is currently available in tablet form in the U.S., is prescribed for the treatment of viral infections associated with herpes viruses. The oral suspension formulation is aimed at providing an alternative for specific patient groups, particularly those with conditions such as chickenpox and herpes zoster. 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 to over 2,56 million patients in the U.S. were filled in 2022[2]. In 2023 more than 577 million tablets were sold in the U.S, growing at a CAGR of 3,5%[3].

Hyloris' novel Valacyclovir oral suspension is designed to offer distinct advantages, including improved dosing accuracy and enhanced stability compared to compounded products, potentially leading to increased patient compliance.

[1] 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 prepared oral suspension of Valtrex® tablets (50 mg/mL) and to Valtrex® tablets, as sold in the U.S.

[2] Drug Usage Statistics, ClinCalc DrugStats Database

[3] 3 years Compound Annual Growth Rate, IQVIA

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 21 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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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,

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