

Hyloris Provides Update on FDA Review of Valacyclovir for Oral Suspension

Liège, Belgium – 19 February 2026 - 7:30 AM CET - Regulated Information – Inside Information - Hyloris Pharmaceuticals SA (“Hyloris”) (Euronext Brussels: HYL) today announces that it has been informed by its manufacturing partner in Greece that the U.S. Food and Drug Administration (FDA) has completed its most recent inspection of the manufacturer’s facility and assigned an Official Action Indicated (OAI) classification, meaning the FDA identified significant inspection observations that require corrective actions by the facility. The manufacturer confirmed that it is actively implementing its remediation plans.

The manufacturer has a well-established track record of pharmaceutical production and supply, serving multiple clients in regulated markets, including the U.S. Following the inspection outcome, the manufacturer has paused the manufacturing of products destined for the U.S. while currently still producing oral dosage forms for markets outside of the U.S.

The New Drug Application (NDA) for Valacyclovir for Oral Suspension remains pending, despite the previously assigned PDUFA target action date of 12 October 2025. To date, Hyloris has responded to all product-related questions raised during the FDA product review. At this stage, no additional action has been communicated to or requested by the FDA from Hyloris and/or its commercial partner. In the current context, Hyloris believes that resolution of the manufacturing situation is required to obtain an FDA product approval and is working on a manufacturing solution for its Valacyclovir product.

Hyloris will provide an update in accordance with regulatory disclosure requirements when further information is available.

About Valacyclovir Oral Suspension

The NDA submission is supported by robust data from two pivotal clinical trials. 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 7,12 million prescriptions to over 2,79 million patients in the U.S. were filled in 2023¹. In 2024 more than 610 million tablets were sold in the U.S, growing at a CAGR of 4,2%². 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 Valacyclovir - Drug Usage Statistics, ClinCalc DrugStats Database

² 3 years Compound Annual Growth Rate, IQVIA



About Hyloris Pharmaceuticals

Hyloris is the specialty biopharma company focused on innovating, reinventing, and optimizing existing medications through reformulation and repurposing to address important healthcare needs and deliver meaningful 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 and regulatory burden required for market entry, and significantly shorten the development timelines, leading to reduced costs and risks. Hyloris has announced a broad development portfolio of 28 products, including 25 value-added medicines of which two products are currently in early stages 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 two high barrier generic products approved in the U.S. and one high-barrier generic product in development. Beyond its announced portfolio, Hyloris has initiated several additional internal early-stage development activities, bringing the total pipeline to more than 30 products and product candidates, and continues to evaluate further product opportunities to support future growth. Hyloris is based in Liège, Belgium and since 2020 listed on Euronext Brussels (EBR: HYL).

For more information, please 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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