Press Release
Regulated Information – Inside information

Hyloris Announces Partnership with Rosemont Pharmaceuticals for Valacyclovir Oral Suspension in the U.S.

Exclusive Licence and Supply Agreement for the U.S. Signed with Rosemont Pharmaceuticals

Liège, Belgium – 9 December 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 an exclusive license and supply agreement with Rosemont Pharmaceuticals ('Rosemont') for its proprietary Valacyclovir oral suspension.

Hyloris previously announced positive data of two pivotal clinical studies[1] that support the preparation of a New Drug Application (NDA) for submission to the U.S. Food & Drug Administration (FDA).

Under the agreement, Hyloris will handle the registration efforts and the supply of the Valacyclovir oral suspension, while Rosemont will undertake the commercialization efforts in the U.S. Hyloris will receive milestone payments and royalties from U.S. product sales, in line with its strategic objectives.

Stijn van Rompay co-Chief Executive Officer of Hyloris commented "We're thrilled to finalize this deal with Rosemont, as it aligns perfectly with our long-term vision. Rosemont's commitment to innovation and commercial excellence makes them an ideal partner, and we're confident this collaboration will deliver exceptional value."

About Valacyclovir Oral Suspension

Valacyclovir, currently commercialized as a tablet in the U.S, is indicated for treating certain viral infections caused by herpes viruses. The oral suspension formulation is aimed at providing an option 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 2,4 million patients in the U.S. were filled in 2020[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, enhanced stability compared to compounded products, potentially leading to increased patient compliance.

[1] Comparing the relative bioavailability of Hyloris' proprietary Valacyclovir Oral Suspension to extemporaneously prepared oral suspension of Valtrex® tablets and with Valtrex® tablets in its solid form

[2] Drug Usage Statistics, ClinCalc DrugStats Database

[3] 3 years Compound Annual Growth Rate, IQVIA

About Rosemont Pharmaceuticals

Rosemont has over 50 years of expertise in the development, manufacture and distribution of oral liquid medicines. Since the release of its first liquid medicine in 1974, Rosemont has continued conducting research, developing, and bringing new products to market advocating support for vulnerable patients with swallowing difficulties. As of 2024, Rosemont has a portfolio of over 130 oral liquid medicines across a range of therapeutic areas including over 100 licensed products in 27 international markets. In July 2024 Rosemont announced the acquisition of Sabal Therapeutics, a US based pharmaceutical company, specialized in liquid medicines, thereby expanding their footprint into the U.S.

Learn more at www.rosemontpharma.com

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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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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