Hyloris Announces Partnerships for Valacyclovir Oral Suspension Covering Canada, Australia, New Zealand and the Netherlands

- Exclusive Commercialisation Agreement for Canada, Australia and New Zealand Signed with AFT Pharmaceuticals
- Exclusive Commercialisation Agreement for the Netherlands Signed with QliniQ

Liège, Belgium – May 13 2025 – 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 and optimizing existing medications, today announces the signing of exclusive commercialisation agreements for its proprietary Valacyclovir oral suspension with AFT Pharmaceuticals and QliniQ. The agreement with AFT Pharmaceuticals covers Canada, Australia, and New Zealand, while QliniQ has secured rights for the Netherlands.

Hyloris has already submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), supported by positive results from two pivotal clinical studies[1]. In addition, a third pivotal study supports the upcoming regulatory submissions in selected European countries. Based on the available data, Hyloris does not expect additional clinical studies are required for approval in the newly partnered territories. Regulatory filings in these countries are planned for 2025.

Thomas Jacobsen and Stijn van Rompay co-Chief Executive Officers of Hyloris commented: “We are thrilled to finalize these agreements, as they align perfectly with our long-term strategy. Canada, Australia and the Netherlands represent attractive markets for Valacyclovir. In particular, Canada is one of the largest consumers of Valacyclovir globally, making it a high priority for us outside the U.S.”

Under the agreements, Hyloris will support the registration efforts, while AFT and QliniQ will be responsible for commercialization in the respective territories. Hyloris will receive up to 50% of the gross margin, after deduction of specified expenses. The agreements do not include any milestone payments.

About Valacyclovir Oral Suspension

Valacyclovir, currently available in tablet form, is indicated for treating certain viral infections caused by herpes viruses. The oral suspension formulation provides an alternative treatment option, particularly for patient groups who may benefit from a liquid form, such as those with chickenpox or herpes zoster. Valacyclovir is available by prescription only, and the dosage and duration of treatment depend on the specific condition being treated and the patient's medical history.

[1] Comparing the relative bioavailability of Hyloris’ proprietary Valacyclovir Oral Suspension to an extemporaneously prepared oral suspension and the conventional tablet formulation

In the targeted markets (Canada, Australia, New Zealand, and the Netherlands) approximately 134 million tablets were sold in 2023, with a compound annual growth rate (CAGR) of 7%[2], generating an annual sales value of USD 64 million.

Hyloris' novel Valacyclovir oral suspension is designed to offer distinct advantages, including improved dosing accuracy, enhanced stability compared to compounded products, which could lead to increased patient compliance and better overall treatment outcomes.

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 22 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 one high barrier generic product launched in the U.S. and two high barrier generic products in development.

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

About AFT Pharmaceuticals Ltd

AFT is a listed (NZE: AFT) and growing multinational pharmaceutical company that develops, markets, and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories. Its business model focuses on developing and in-licensing patented, branded, and generic products for commercialization. AFT Pharmaceuticals has direct operations in Australia, New Zealand, Singapore, Hong Kong, South Africa, Canada, and the United Kingdom and has out-licensed products to licensees and distributors in over 120 countries worldwide.

Learn more at www.aftpharm.com/

About QliniQ

QliniQ is a Dutch company which develops and in-licenses pharmaceuticals and medical devices and commercializes these in the Netherlands. QliniQ nurtures cooperation and long-lasting business relationships with international companies as part of its successful market approach.

[2] IQVIA 2021 - 2023

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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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