Hyloris Broadens Pipeline with Ready-To-Use Pantoprazole IV

- Licensing Agreement Signed for Innovative Technology to Develop a Novel, Ready-To-Use ('RTU") Formulation of Pantoprazole IV for Worldwide Commercialization
- A Breakthrough in Speed, Efficiency and Convenience for Healthcare Providers

Liège, Belgium – 13 February 2025, 06:00 PM 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 that it has entered into an exclusive licensing agreement to develop a ready-to-use formulation for intravenous (IV) administration of pantoprazole, a molecule used to treat gastric acid-related conditions.

The new ready-to-use pantoprazole formulation represents a substantial advancement over the existing lyophilized (freeze-dried) version, which requires reconstitution prior to administration. Reconstitution is a more complex and resource-intensive process that adds unnecessary preparation time, effort, and cost for administration. In contrast, the ready-to-use formulation eliminates the need for reconstitution, offering an immediate and efficient solution for healthcare professionals.

Thomas Jacobsen, Co-Chief Executive Officer and Chief Business Development Officer of Hyloris commented, "The shift from a lyophilized product to a ready-to-use formulation underscores our commitment to advancing healthcare delivery. This innovation is particularly valuable in high-demand or time-sensitive environments. This novel ready-to-use formulation maintains the same potency as the lyophilized version, ensuring consistent therapeutic efficacy and brings a solution to healthcare systems worldwide that has a greater ease of use, simplifies administration, reduces preparation time, and improves cost efficiency."

In 2023, over 351 million vials of lyophilized pantoprazole IV were sold worldwide, generating a global revenue estimated of over USD 454 million[1].

Stijn Van Rompay, CEO of Hyloris added "With this first new product candidate announcement this year, we are further enhancing our mission to improve patient care and treatment options. Hyloris aims to enter its first markets in about 3 years, and anticipates that solutions like this could capture double-digit market share in terms of volume. We currently project to keep the development costs well below EUR 5 million."

After recouping development costs, Hyloris will pay the licensor a single-digit percentage of net profits generated by the Company as a royalty.

[1] IQVIA

Pantoprazole IV, a flagship product for managing conditions caused by gastric acidity

Pantoprazole for intravenous administration (IV) was launched in 2001 and is primarily available as a 40 mg/vial presentation. It is currently only available as a lyophilized product, which requires reconstitution before use[2]. Once reconstituted, the drug is usually diluted and administered via infusion over 15–30 minutes or longer, depending on the prescribed dosage.

This intravenous formulation was developed to provide an alternative route of administration for patients unable to take pantoprazole oral medication, such as those who are critically ill or recovering from surgery. Pantoprazole IV became a key option in managing severe acid-related conditions, including bleeding peptic ulcers and erosive esophagitis, by delivering the medication directly into the bloodstream for faster acid suppression and symptom relief. It belongs to a class of drugs called proton pump inhibitors (PPIs), which work by blocking the proton pump in the stomach lining responsible for acid secretion.

In 2023, over 351 million vials of pantoprazole IV were sold globally, marking a 10% increase from 2022, with 30 million vials sold in the U.S. alone. Market revenues are projected to expand at a compound annual growth rate (CAGR) of 12,7% from 2024 to 2031[3]. Key factors driving this growth include the increasing prevalence of gastrointestinal disorders, a rising geriatric population, and the growing adoption of injectable forms of medication due to their rapid therapeutic effects. The market benefits from advances in healthcare infrastructure and the rising awareness of proton pump inhibitors in managing acid-related conditions[4].

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For more information, contact Hyloris:

Stijn Van Rompay, Co-CEO
Stijn.vanrompay@hyloris.com
+32 (0)4 346 02 07

Thomas Jacobsen, Co-CEO
Thomas.jacobsen@hyloris.com
+32 (0)478 27 68 42

[2] Pantoprazole has also been approved by the U.S. FDA as a frozen, ready to use premix intravenous formulation, which requires thawing before administration. No sales were recorded in IQVIA for 2023.
[3] IQVIA
[4] Pantoprazole Sodium For Injection Research Reports | Reliable business arena

About Hyloris Pharmaceuticals SA

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 existing regulatory pathways, such as the FDA's 505(b)2 pathway in the U.S or similar regulatory frameworks in other region which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This type of regulatory pathway can reduce the clinical burden required to bring a product to market, and significantly shorten the development timelines and reduce costs and risks.

Hyloris has built a broad, patented portfolio of 20 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Two products are currently in early phases of commercialization with partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. Outside its core strategic focus, the Company also 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.

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 Issuer 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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