Hyloris Announces Strategic Partnership with Orion for its RTU Pantoprazole IV in European Markets

Exclusive License and Supply Agreement Grants Orion Rights to Commercialize Ready-to-Use Pantoprazole IV in the European Union, the UK, Switzerland and Norway

Liège, Belgium – 19 January 2026 – 09:30 PM CET – Regulated Information – Inside information - Hyloris Pharmaceuticals SA ("Hyloris") (Euronext Brussels: HYL), the specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that it has entered into an exclusive license and supply agreement with Orion Corporation ("Orion"). The agreement grants Orion the rights to register, market, and commercialize ready-to-use Pantoprazole Intravenous, a product designed to treat gastric acid-related conditions, in the European Union, the UK, Switzerland and Norway.

The new ready-to-use pantoprazole intravenous formulation ("RTU IV") 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 to the administration. In contrast, the ready-to-use formulation eliminates the need for reconstitution, offering an immediate and efficient solution for healthcare professionals.

Under the terms of the agreement, Orion will be responsible for the regulatory, marketing and commercialization of the product, leveraging its strong presence in hospital and specialty care markets. Hyloris will support the collaboration through its regulatory and technical expertise and will supply the product through its established manufacturing network. Hyloris is eligible to receive upfront and milestone payments, together with ongoing revenues representing a substantial minority share of the in-market sales, subject to agreed minimum pricing thresholds.

Stijn van Rompay, Chief Executive Officer of Hyloris, commented*: "It has been less than a year since we announced this product candidate and we are encouraged by the speed at which it has progressed. Based on our experience, we are confident that once launched, this asset has the potential to deliver our usual significant target return on our investment. Pantoprazole remains an important therapy in hospital care, and we see clear value in a ready-to-use injectable formulation. We look forward to progressing its regulatory and commercial development*."

Thomas Jacobsen, Chief Business Development Officer of Hyloris, added: "*We are pleased to expand our collaboration with Orion through this agreement for our ready-to-use pantoprazole injection. Orion is a highly respected partner with a strong footprint in hospital markets, and we believe this collaboration further validates Hyloris' strategy of creating differentiated, practical pharmaceutical solutions based on well-established molecules".*

About Pantoprazole IV

Pantoprazole is a widely used proton pump inhibitor for the treatment of gastric acid–related disorders across care settings. In hospitals, intravenous pantoprazole is the standard of care, particularly for acute and severe indications and for patients who are unable to take oral medication. As a proton pump inhibitor, pantoprazole provides rapid and effective suppression of gastric acid secretion and plays a critical role in the management of conditions such as bleeding peptic ulcers, erosive esophagitis, and stress ulcer prophylaxis in critically ill or post-surgical patients.

In 2024, over 50 million vials of lyophilized pantoprazole IV were sold in the targeted territory[1]. Despite its widespread use, currently marketed pantoprazole IV products are lyophilized formulations that require multiple preparation steps prior to administration. Reconstitution is time-consuming, resource-intensive, and adds operational complexity for hospital pharmacies and nursing staff, particularly in high-acuity or high-volume hospital environments.

Hyloris' novel ready-to-use intravenous pantoprazole formulation represents a clear advancement over existing lyophilized products. By eliminating the need for reconstitution, the product simplifies preparation and administration, reduces handling time, and improves ease of use for healthcare professionals. This results in improved workflow efficiency, reduced labour burden, and potential cost savings at the hospital level. Importantly, the ready-to-use formulation maintains equivalent potency and therapeutic efficacy compared to lyophilized pantoprazole IV, ensuring consistent clinical outcomes without requiring changes to established treatment protocols.

About Hyloris Pharmaceuticals

Hyloris is a 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 payers. 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 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 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 additional 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, visit www.hyloris.com and follow-us on LinkedIn.

About Orion Corporation

Orion is a globally operating Nordic pharmaceutical company – a builder of well-being for over a hundred years. We develop, manufacture and market human and veterinary pharmaceuticals and active pharmaceutical ingredients. Orion has an extensive portfolio of proprietary and generic medicines and consumer health products. The core therapy areas of our pharmaceutical R&D are oncology and pain. Proprietary products developed by Orion are used to treat cancer, neurological diseases and respiratory diseases, among others. In 2024, Orion's net sales amounted to over EUR 1.5 Billion, and the company employed about 3,700 professionals worldwide, dedicated to building well-being. Orion's A and B shares are listed on Nasdaq Helsinki.

For more information, please visit www.orionpharma.com.

[1] IQVIA MAT Q1 2025

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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. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.
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