Hyloris Expands Pipeline with a New Product Candidate for Equine Gastric Ulcer Syndrome

- Development of a Novel Long-Acting Injectable Formulation of a Proton Pump Inhibitor for the Treatment of Equine Gastric Ulcer Syndrome (EGUS)
- Currently, No Approved Long-Acting Injectable Treatment for EGUS Commercially Available
- Hyloris' Product Portfolio Has Expanded to 22, with Three Products Commercially Available

Liège, Belgium – 19th of August 2024 – 07.00am CET – Regulated Information – Inside Information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through drug repurposing and reformulation, today announces the development of HY-095, a long-acting injectable formulation of a well-known Proton Pump Inhibitor (PPI) designed to treat Equine Gastric Ulcer Syndrome (EGUS).

***Thomas Jacobsen and Stijn Van Rompay,* Co-Chief Executive Officers of Hyloris**, stated: "Equine Gastric Ulcer Syndrome is a common and painful condition affecting many horses, often impacting their performance and well-being. Our innovative long-acting injectable product candidate, targets to offer a solution that ensures reliable drug delivery while minimizing the frequency of dosing, providing a much-needed option for both veterinarians and horse owners. The development pathway for veterinary drugs closely resembles the pathway used for human medications."

Hyloris has secured a development partner that has product specific proprietary technology and intellectual property under development. Under the agreement the partner will manage the drug and device development within a predefined budget. Hyloris will manage the clinical trials and fund the development costs which are currently projected to remain well below €7 million. After the development costs are recovered, the profits will be shared, with Hyloris entitled to retain up to 90% of the net margin. Hyloris has also obtained an option to extend the license for development for human use under comparable financial terms.

A global commercialization will be pursued through strategic partnerships, targeting all relevant markets.

About EGUS

EGUS, or Equine Gastric Ulcer Syndrome, is a condition in horses characterized by the development of ulcers in the lining of the stomach. A gastric ulcer occurs when the lining has been damaged by stomach acid and digestive enzymes. EGUS is a widespread condition affecting millions of horses globally and causes significant discomfort, weight loss, and reduced performance. Ulcers can be found

in approximately 30% of adult horses[1]. The condition is particularly prevalent in high-performance horses, with up to 90% of racehorses and up to 60% of sport horses experiencing[2].

About PPIs for EGUS

Proton Pump Inhibitors (PPIs) are a class of medications that block the proton pump to reduce the gastric acid secretion. Current treatment for EGUS typically involves daily oral administration of omeprazole (a PPI) for a 28-day course with the possibility of a 14-day extension. Despite the effectiveness of PPIs in suppressing gastric acid production and treating EGUS, the oral formulation can present several limitations. These include necessity for daily dosing, resistance from the horse, inconsistent dosing and adherence, low bioavailability, and variability in absorption resulting in suboptimal ulcer management.

Estimates suggest that the market for products to prevent, manage, and treat EGUS is substantial, given the high prevalence and cost of treatment. The approved drug therapy market is estimated at a value of USD 188 million for 2024[3]. The growing awareness of equine assisted therapies and their benefits have contributed to the continued market expansion.

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 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.

[1] Stomach (Gastric) Ulcers in Horses - Horse Owners - Merck Veterinary Manual (merckvetmanual.com)
[2] https://www.westvets.com.au/gastric-ulcers-in-the-performance-horse/
[3] Maia Research Analysis, Global Equine Pharmaceuticals and Supplements Industry Market Research Report

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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.