Hyloris Announces Positive IDMC Recommendation to Continue Alenura® Study Following Interim Assessment

- The Independent Data Monitoring Committee (IDMC) Recommends Continuation of the Alenura Clinical Trial Following Interim Assessment
- Enrollment Completion Expected by the End of 2025
- Potential First-Line Treatment for Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS)

Liège, Belgium – 19 March 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 the Independent Data Monitoring Committee (IDMC), an independent panel of experts in biostatistics, clinical research, and ethics, conducted a thorough review of the available data on Alenura. Their assessment concluded that there were no safety concerns warranting trial termination and that the efficacy signals observed justified continued investigation and patient recruitment.

Alenura, an investigational therapy currently in advanced-stage development by the Company's drug development partner Vaneltix Pharma, Inc., is being evaluated for its efficacy and safety in treating Interstitial cystitis/bladder pain syndrome (IC/BPS). The ongoing Phase 2 trial compares Alenura to both of its individual components (heparin and lidocaine) as well as placebo. The trial, which commenced mid-2023, reached a pre-specified interim analysis milestone, enabling the IDMC to assess unblinded data on safety, efficacy, and overall trial conduct.

"This recommendation from the IDMC is a crucial milestone in the development of Alenura." said Stijn Van Rompay, Co-Chief Executive Officer of Hyloris. "It reinforces our confidence in the potential of this therapy and allows us to proceed as planned toward the next stages of clinical evaluation."

Dr. Dan Vickery, Chief Executive Officer of Vaneltix Pharma, commented: "IC/BPS is a chronic bladder condition that results in recurring discomfort or pain in the bladder and surrounding pelvic region. Today, there is no cure available, and we know of no products specifically approved to treat acute bladder pain. Alenura has the potential of becoming a first-line drug treatment for acute pain in patients with interstitial cystitis/bladder pain syndrome."

The study will continue, with further patient recruitment and ongoing data collection to assess outcomes. Final results are anticipated to be available within the next 12 months, which will inform regulatory discussions and potential market approval strategies.

About Alenura
Alenura is a patented, innovative, clinical-stage bladder instillation product candidate that combines lidocaine, a well-established anesthetic, in a new alkalinized form, with heparin, a glycosaminoglycan (GAG) component of bladder mucous membranes[1]. This combination aims to provide immediate pain relief and augment the bladder's mucous layer. In previous controlled clinical trials, Alenura was well-tolerated and suggested to be more effective in terms of pain relief, urgency response, and improvement of symptoms compared to placebo, heparin alone, and lidocaine alone.

About the Phase 2 Trial
The primary endpoint will be to evaluate the change in sum of bladder pain intensity differences from baseline to 12 hours (SPID-12) after administration of Alenura compared with the SPID-12 after administration of its individual active components (lidocaine and heparin), and to placebo as determined by using the 11-point NRS (numerical rating scale) for bladder pain. Following the recommendation of the IDMC, the trial's enrolment target will be adjusted but will remain below the maximum of 180 subjects across multiple sites in the United States. Each subject will receive a single blinded dose of Alenura, placebo, lidocaine, or heparin by random assignment.

As of 2025, a second Phase 2 clinical trial of Alenura is in progress—a two-week, open-label study evaluating the administration of multiple doses in subjects experiencing episodes of acute bladder pain.

About IC/BPS
IC/BPS is a condition that results in recurring discomfort or pain in the bladder and surrounding pelvic region. The scientific team of Vaneltix, led by Dr. CL Parsons, a distinguished Professor Emeritus, Urologist, and Surgeon, believes that IC/BPS stems from an anatomical defect in the protective bladder lining (the GAG mucous layer), which exposes nerve endings to toxic components in urine. Patients often experience episodes of moderate or severe intensity pain lasting hours to days (painful flares), which require treatment. IC/BPS is more prevalent in women, although men can experience symptoms as well. Although underdiagnosed, it is estimated that at least 6 million people in the U.S. suffer from the condition[2].

About Vaneltix
Vaneltix Pharma, Inc. is a specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products focused on repurposed products that can be developed through the FDA 505(b)(2) regulatory pathway and other de-risked programs. Vaneltix's development programs target significant unmet medical need and major market opportunities in urology and women's health care. Vaneltix's lead clinical program is Alenura®.

For further information, please visit Vaneltix's website at http://www.vaneltix.com.

[1] Lidocaine is a local anesthetic that temporarily numbs the skin and mucous membranes by blocking nerve signals. Heparin is also an anticoagulant (blood thinner) used to prevent blood clot formation.

[2] RAND study, J Urol. 2011 August; RICE study, J Urol. 2013 January

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 21 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.

******

For more information, contact Hyloris Pharmaceuticals:

Stijn Van Rompay, co-CEO
stijn.vanrompay@hyloris.com

Thomas Jacobsen, co-CEO
thomas.jacobsen@hyloris.com

32 (0)4 346 02 07

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.

This press release contains information about a product under development and is not intended as a promotional statement. The product mentioned is subject to regulatory approval and is not currently available for sale. Please consult licensed medical professionals for healthcare decisions.