Hyloris announces enrolment of first patient in a 4-arm clinical trial of Alenura™

- Potential first-line treatment for interstitial cystitis/bladder pain syndrome (IC/BPS)
- Global opportunity with a patient population of at least 6 million in the U.S. alone[1]

Liège, Belgium – 22 June 2023 – 7AM CET – Non-regulated 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 first patient has been enrolled in a 4-arm Phase 2 trial[2] of Alenura™, comparing the product candidate to both of its individual components (heparin and lidocaine)[3] as well as placebo. Alenura™ is a patented, innovative, clinical-stage bladder instillation product candidate that combines lidocaine, a well-established anaesthetic, in a new alkalinized form with heparin, a glycoso-amino-glycan (GAG), a component of bladder mucous membranes.

Alenura™ has the potential of becoming a first-line drug treatment for acute pain in patients with interstitial cystitis/bladder pain syndrome.

Thanks to the novel dual mode-of-action, Alenura™ has the unique potential to i) immediately relieve pain, and ii) augment the mucous layer of the bladder. In previous controlled clinical trials[4], Alenura™ was well-tolerated and suggested the drug product candidate was more effective in terms of pain relief, urgency response and improvement of symptoms compared to placebo, heparin alone and lidocaine alone.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "Currently there are no drug products specifically approved to treat acute bladder pain in patients with IC/BPS. Alenura™ holds

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

[2] Study published on clinicaltrials.gov on February 21st, 2023

[3] Lidocaine is a local anaesthetic that works by causing temporary numbness/loss of feeling in the skin and mucous membranes; Heparin is a component of the mucous layer of the bladder wall and is an anticoagulant (blood thinner) that prevents the formation of blood clots

[4] One study compared Alenura to placebo, a second study compared Alenura to its individual components heparin and lidocaine, and placebo

the promise of a ready-to-use solution to be administered by physicians. We are highly motivated to offer relief to these patients by improving the symptoms disrupting their daily lives."

"This ambitious phase 2 program includes additional clinical trials, potentially reducing time and number of patients needed in Phase 3 trials, in order to help patients waiting for an efficient treatment sooner rather than later."

Alenura™ is being developed in partnership with Vaneltix Pharma, Inc (Vaneltix), the sponsor of the clinical trial. Hyloris has committed to staged investments of in total maximum USD 6.7 Mio for multiple Phase 2 trials (4-arm, multi-dosage, PK), manufacturing and regulatory related activities, and a loan of USD 0.5 Mio.

Hyloris will be eligible to receive a tiered percentage of the product margin generated by Alenura™.

About this Phase 2 Trial

Vaneltix is the sponsor of the phase 2 clinical program. 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.

The trial will enrol a target of 120 patients across multiple sites in the United States. Each subject will receive a single blinded dose of Alenura™, placebo, lidocaine, or heparin by random assignment.

About Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS) and Alenura™

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. C. Lowell Parsons, a distinguished Professor Emeritus, Urologist and Surgeon, believes that ICS/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 severe intensity pain lasting hours to days (painful flares), which requires treatment. IC/BPS is more prevalent in women, although men can experience symptoms as well, and although underdiagnosed, it is estimated at least 6 million people in the U.S. suffer from the condition.

Alenura™ is a unique, combination product of alkalinised lidocaine and the glycosaminoglycan heparin. Alkalinised lidocaine penetrates the transitional epithelial cell layer and provides immediate

pain relief. Whereas heparin sodium is thought to augment the natural mucous layer of the bladder to prevent further irritation of the bladder and prolong the anaesthetic effect. Alenura™ will be supplied as a prefilled syringe for intra-vesicular administration to the bladder through an installation procedure and is protected by multiple patents and patent applications potentially providing exclusivity up to 2038.

About Hyloris

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. Hyloris has built a broad, patented portfolio of 16 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Outside of its core strategic focus, the Company also has 3 high barrier generic products in development.

Two products are currently in initial phases of commercialization with partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. The Company's development strategy primarily focuses on the FDA's 505(b)2 regulatory pathway, which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This 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 is based in Liège, Belgium. For more information, visit www.hyloris.com and follow-us on LinkedIn.

For more information, contact Hyloris:

Stijn Van Rompay, CEO
stijn.vanrompay@hyloris.com
+32 (0)4 346 02 07
Jean-Luc Vandebroek, CFO
jean-luc.vandebroek@hyloris.com
+32 (0)478 27 68 42
Sven Watthy, Investor Relations & Communications manager
Sven.watthy@hyloris.com
+32 (0)499 71 15 29

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.