Press Release
Regulated Information

Hyloris Enters into Strategic Partnership with Vaneltix for Treatment of Acute Pain in Interstitial Cystitis

Access to Alenura™, a dual mode-of-action advanced clinical candidate for the treatment of acute pain in interstitial cystitis/bladder pain syndrome (IC/BPS)

Addressable patient population of at least 6 million[1] in the U.S.

Liège, Belgium – 17 December 2021 – 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 a strategic collaboration with Vaneltix Pharma, Inc. for the development and commercialisation of Alenura™ as first-line drug treatment for acute pain in interstitial cystitis /bladder pain syndrome (IC/BPS).

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 component of mucous membranes[2]. 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 clinical studies, Alenura™ was well-tolerated and demonstrated to be more effective in terms of pain relief, urgency response and improvement of symptoms compared to placebo, and lidocaine alone[3].

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 there are no products specifically approved to treat acute bladder pain. We have discovered and developed AlenuraTM to address these unmet medical needs and are very excited to partner with Hyloris to further develop AlenuraTM and bring much needed innovation to IC/BPS patients."*

Stijn Van Rompay, Chief Executive Officer of Hyloris, added: "*With Alenura™, we are expanding our broad, patented value-added portfolio with a fourth new asset this year, delivering on our promise. The partnership with Vaneltix also perfectly fits within our strategy of increased focus towards repurposed medicines and addressing unmet medical needs to create a meaningful difference for patients. We are now preparing the next steps and anticipate the start of a larger Phase 2 comparative study and a Phase 2 multidose study mid 2022 for which the results could be available by late 2023."*

Under the terms of the agreement, Vaneltix will be responsible for the further development, manufacturing, regulatory affairs and commercialisation of Alenura™ in collaboration with Hyloris. In return, Hyloris will provide staged investments of in total maximum USD 6.7 Mio for Phase 2, 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 Vaneltix.

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. CL 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

[1] RAND study, J Urol. 2011 August; RICE study, J Urol. 2013 January
[2] 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
[3] Http://www.vaneltix.com/therapies/alenura/

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[1] 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 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. 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™, a proprietary combination of the approved drugs lidocaine and heparin that is instilled into the bladder, and targets IC/BPS, an unmet medical need which affects at least 6 million [1] men and women in the US. For further information, please visit Vaneltix's website at http://www.vaneltix.com.

About Hyloris Pharmaceuticals

Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimising 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 15 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 and registration phase. Two products are currently in initial phases of commercialisation 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, please contact:

Hyloris Pharmaceuticals, Investor Relations and Media
investorrelations@hyloris.com

For further information on the agreement with Vaneltix, please consult the public announcement in accordance with Article 7:97, §4/1 of the Code of Companies and Associations, which is available on the Hyloris website: https://hyloris.com/wp-content/uploads/2021/12/RP-Vaneltix.pdf

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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 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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