Alenura® Delivers Positive Phase 2 Results in Interstitial Cystitis/Bladder Pain Syndrome Trial

Primary endpoint met with statistically significant superiority across all three comparisons

Liège, Belgium – 8 November 2026 – 7.00 PM CET – Regulated Information – Inside Information – Hyloris Pharmaceuticals SA ("Hyloris") (Euronext Brussels: HYL), the specialty pharma group committed to addressing unmet medical needs through reinventing existing medicines and smart NCE developments, and Vaneltix Pharma, Inc. ("Vaneltix"), a biotechnology company focused on developing treatments addressing unmet needs in women's healthcare and urology, today announce positive and statistically significant Phase 2 efficacy results from the VNX001-111 clinical study evaluating Alenura® for the treatment of acute bladder pain associated with interstitial cystitis/bladder pain syndrome (IC/BPS):

- **Primary endpoint met:** Alenura®, demonstrated statistically significant superiority in bladder pain relief versus placebo and each individual component, alkalinized lidocaine and heparin (all reported p-values <0.01).
- **Benefit beyond the primary endpoint at 12h:** Alenura® also demonstrated positive pain-relief results at 24 hours, beyond the 12-hour primary assessment supported by positive patient-reported symptom improvement results.
- **Significant unmet need:** An estimated six million or more people in the U.S. experience symptoms consistent with IC/BPS, with no FDA-approved treatment specifically for acute IC/BPS bladder pain.
- **Continued development:** Positive results support ongoing development activities and preparations for a U.S. 505(b)(2) New Drug Application (NDA), subject to completion of the remaining clinical and regulatory requirements.

Positive Phase 2 results demonstrate the combination's added benefit

In the four-arm VNX001-111 study conducted by Vaneltix, a single bladder instillation of Alenura® was compared with placebo and each of its individual components administered alone. The study met its primary endpoint, sum of bladder pain intensity differences over 12 hours (SPID-12), with statistically significant superiority versus all three comparators (all reported p-values <0.01). Pain-relief assessments at 24 hours also favoured Alenura®, with additional supportive results from patient-reported symptom improvement assessments.

Demonstrating superior pain relief of Alenura®, compared with each of its components, including lidocaine alone, supports the clinical rationale for combining the active ingredients into a proprietary formulation and provides an encouraging foundation for continued development.

Significant unmet need in acute bladder pain

An estimated six million or more people in the U.S. experience symptoms consistent with IC/BPS, predominantly women. Patients can experience recurrent flares of moderate-to-severe bladder pain, yet no therapy is specifically FDA-approved for these acute episodes. Alenura® is being developed as a ready-to-use treatment administered directly into the bladder during a painful flare.

Next steps in the development program

Additional development activities are ongoing to support preparations for a 505(b)(2) New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA).

Stijn Van Rompay, CEO of Hyloris, commented: "*The outcome of this study is particularly encouraging, as demonstrating an additional benefit over two active components represents a significant clinical hurdle. These findings strengthen our confidence in Alenura®'s potential to address an important unmet medical need. Our shared goal is to bring meaningful relief to patients experiencing acute bladder pain associated with IC/BPS.*"

Dan Vickery, CEO of Vaneltix, added: "*We are very pleased that the results of this Phase 2 study support our efforts to bring relief to patients living with this debilitating condition. With the support of our partner Hyloris, we are eager to generate the remaining evidence needed to seek regulatory approval, in the U.S. and other jurisdictions."*

About Alenura®

Alenura® is a patented, ready-to-use bladder instillation in clinical development for acute IC/BPS pain flares. It combines alkalinized lidocaine, a well-established local anesthetic intended to provide rapid pain relief, with heparin, intended to support the bladder's protective lining and potentially help sustain pain relief. Alenura® is protected by multiple patents and patent applications, potentially providing exclusivity until 2038.

About the VNX001-111 Phase 2 Study

VNX001-111 (ClinicalTrials.gov: NCT05737121) was a randomized, double-blind, placebo-controlled, four-arm Phase 2 study conducted at sites across the U.S. It evaluated 153 adults with IC/BPS during an episode of acute moderate-to-severe bladder pain. Each participant received a single bladder instillation of Alenura® (VNX001), placebo, alkalinized lidocaine or heparin alone. The primary endpoint was SPID-12, comparing Alenura® with placebo and each of its individual components.

About Interstitial Cystitis/Bladder Pain Syndrome

IC/BPS is a chronic, debilitating condition characterized by recurring pain or discomfort in the bladder and pelvic region, often with urinary urgency and frequency. Acute pain flares can last from several hours to several days. The condition mainly affects women, is believed to be significantly underdiagnosed, and has no cure.

About Hyloris Pharmaceuticals

Hyloris is a specialty pharma group focused on 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 including more than 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 and commercialized in the U.S.: Podofilox Gel and Tranexamic Acid RTU. 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. Where others stop, Hyloris starts and adds value through Reinventing Existing Medicines for unmet patient needs worldwide. Hyloris is based in Liège, Belgium and since 2020 listed on Euronext Brussels (XBR: HYL) with about 54 people across 13 nationalities, targeting time-to-market of 7 years at an average cost of EUR 7 million per product (non-inflation adjusted).

For more information, visit www.hyloris.com and follow us on LinkedIn.

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About Vaneltix Pharma, Inc.

Vaneltix Pharma is a private, clinical-stage biotech developing treatments for urologic conditions with high unmet need, with a focus on bladder conditions that primarily affect women and on Women's Health Care (WHC). Vaneltix reformulates and enhances existing drugs using the 505(b)(2) and full NDA regulatory pathways on de-risked assets. Alenura® is Vaneltix' lead clinical program. For more information, visit www.vaneltix.com.

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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.
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