Hyloris and Purna Female Healthcare Announce Positive Results from Phase 2 Trial in Patients with Acute Vulvovaginal Candidiasis (VVC)

- Both treatment arms with the combination of Miconazole (2%) and Domiphen Bromide (0.14% or 0.29%) demonstrated excellent safety and tolerability
- Low dose (0.14%) showed significant improvement over active control in clinical and mycological outcome at day 29[1]

Liège, Belgium – 30 January 2024, 07:00 AM 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 positive results for the phase 2 trial of Miconazole Domiphen-Bromide (MCZ-DB) in patients with acute vulvovaginal candidiasis.

The phase 2 trial of MCZ-DB was a 12-week, randomized, double-blind, active-controlled, dose finding trial evaluating the safety and efficacy of two doses of MCZ-DB (MCZ 2% combined with 0.14% or 0.29% of DB) administered once per day for 7 days in patients with acute vulvovaginal candidiasis. The study has been conducted in Belgium with a total of 102 patients enrolled. Efficacy was evaluated by assessing the clinical outcome and mycological outcome to the treatment. A positive clinical outcome is a resolution of VVC signs and symptoms whereas the mycological outcome is determined by a vaginal swab indicating the absence of Candida species yeast.

Top line results are summarized:

- At day 29[1], day 57 and day 85, the low dose (MCZ and 0.14% of DB) demonstrated superior efficacy compared to the active control (MCZ).
- At day 15, both doses administered demonstrated positive safety and tolerability without significant superiority over the active control.
- MCZ-DB was well tolerated in both dose cohorts, with no reported serious adverse events.
- Following the treatments, there was no indication of systemic exposure to Domiphen Bromide.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"I am thrilled to announce promising outcomes for MCZ-DB, showcasing outstanding safety and tolerability in both cohorts. Additionally, the low dose demonstrated significant superiority over the active control by day 29[1]. The primary objective of this trial was to identify the most effective dosage of DB (0.14% or 0.29%) for treating VVC. With these encouraging findings, we are now prepared to engage in discussions with relevant authorities for further clinical investigations".*

About severe and recurring VVC and MCZ-DB

VVC is a prevalent vaginal fungal infection primarily caused by the yeast Candida albicans, affecting as many as one in every two women during their life, with about 175 million units (treatments) sold annually worldwide[2]. Up to 20% of VVC patients develop severe to recurrent VVC characterized by reinfection occurring more than four times per year. These are long-term conditions that cause significant pain and distress, with an estimated economic burden from lost productivity projected up to $14.39 billion annually by 2030[3]. There is a high unmet need for novel treatment options in severe

[1] p-value <0.05
[2] FIOR Markets 2019; Global Info Research; IMS
[3] D.W Denning *et al.*. Lancet Infectious Diseases (2018); D Rosati D *et al.*, An Immunological Perspective, Microorganisms (2020)

and rVVC as current standard of care treatments have significant drawbacks, including lack of efficacy, the development of drug resistance due to continued use and liver toxicity[4]. Preclinical studies have demonstrated that the activity of Miconazole (MCZ), the current topical standard of care, when combined with the Miconazole potentiator Domiphen Bromide, can combat the occurrence and recurrence of mucosal biofilm-related vaginal Candida infections[5]. MCZ and DB work synergistically where DB increases the permeability of the plasma membrane and the vacuolar membrane of Candida spp., and MCZ acting fungicidal, thereby destroying fungal activity and potentially preventing further fungal growth. The synergistic mode-of-action of topical MCZ-DB has the potential to be effective against azole-resistant infections, possibly addressing the high unmet needs in recurring VVC[6].

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 18 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.

About Purna Female Healthcare NV
Purna Female Healthcare is a spin-off of Purna Pharmaceuticals, a family-owned Belgian company specialized in the development and manufacturing of pharmaceutical products. With proficiency in every facet of drug development and manufacturing, Purna Pharmaceuticals can seamlessly progress from the initial stages of innovative ideas or technologies to the industrial production of the final product.

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[4] P.G. Pappas *et al.*, Clinical Infectious Diseases (2016); J.D. Sobel *et al.*, Expert Opinion on Pharmacotherapy (2018)
[5] J Tits., J *et al.*, Antimicrob. Agents Chemother (2020); K. De Cremer *et al.*, Antimicrobial agents and chemotherapy (2015)
[6] Manuscript for scientific paper submitted

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.