

## Hyloris and Purna Female Healthcare announce partnership to develop novel women's health product

*Novel, dual mode-of-action combination product for the treatment of severe and recurrent vulvovaginal candidiasis (rVVC)*

[Webcast](#) with Prof. dr. Donders (KOL) and management today at 4pm CET/10am EST

**Liège, Belgium – 5 February 2021 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL)**, an innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals, and **Purna Female Healthcare** ("PFH"), a spin-off founded by Purna Pharmaceuticals NV and Creafund NV, today announce that they have entered into a partnership to develop and commercialise an innovative combination therapy for the treatment of severe and recurrent vulvovaginal candidiasis (rVVC).

PFH is a special purpose vehicle founded to exclusively develop a local topical combination formulation of the well-known antifungal Miconazole with Domiphen Bromide (MCZ-DB). Under the terms of the agreement, Hyloris has committed to milestone related investments of up to €4.3 million in PFH (of which €1.27 million at signing) and will lead the commercialisation and out-licensing activities. Hyloris owns 20% of PFH and is eligible to receive up to a maximum of 45% of the net profits generated by PFH.

VVC is a vaginal fungal infection commonly caused by the yeast *Candida albicans*, affecting as many as one in every two women during their life, with about 175 million units sold per year globally.<sup>1</sup> Up to 20% of VVC patients develop severe to recurrent VVC where reinfection occurs 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 of up to \$14.39 billion annually by 2030.<sup>2</sup> There is a high unmet need for novel treatment options in severe 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.<sup>3</sup>

Recent 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<sup>4</sup>. 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 effectively destroying fungal activity and 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 complicated and recurrent VVC.<sup>5</sup>

Purna Female Healthcare has exclusively in-licensed MCZ-DB and associated IP owned by KU Leuven and the University of Antwerp (Belgium).

**Stijn Van Rompay, Chief Executive Officer of Hyloris, commented:** *"Patients with severe and rVVC have limited effective treatment options and we believe that the novel MCZ-DB combination therapy has significant potential to help women manage this underserved condition. The strong scientific rationale and proven efficacy and safety profile of MCZ provide further upside and dramatically reduce*

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<sup>1</sup> FIOR Markets 2019; Global Info Research; IMS

<sup>2</sup> D.W Denning *et al.*. Lancet Infectious Diseases (2018); D Rosati D *et al.*, An Immunological Perspective, Microorganisms (2020)

<sup>3</sup> P.G. Pappas *et al.*, Clinical Infectious Diseases (2016); J.D. Sobel *et al.*, Expert Opinion on Pharmacotherapy (2018)

<sup>4</sup> J Tits, J *et al.*, Antimicrob. Agents Chemother (2020); K. De Cremer *et al.*, Antimicrobial agents and chemotherapy (2015)

<sup>5</sup> Manuscript for scientific paper submitted

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*potential development risk, time, and cost. We are very pleased to have entered into this agreement with Purna Female Healthcare to deliver a much-needed innovation in women's health, demonstrating our ability to identify and reformulate known products to enhance current treatment practices."*

**Bart Peeters, Managing Director of Purna Female Healthcare, added:** *"rVVC is a chronic debilitating condition on which we have done four years of research together with our long-term strategic partner Creafund, and with KU Leuven and the University of Antwerp. We are all excited to work together with Hyloris to further progress this much needed novel combination therapy. By combining our long-term expertise in development and manufacturing of pharmaceutical products, with Hyloris' focus on the development and commercialisation of high-value products, we believe we are well placed to rapidly bring MCZ-DB to patients. We look forward to commencing clinical trials in 2021 and to providing further updates as we reach significant product development milestones."*

### **Webcast and presentation**

Prof. dr. Gilbert Donders, Key Opinion Leader (KOL) and Gynaecologist at the Antwerp University Hospital, Belgium, and Hyloris and PFH management will host a conference call /webcast presentation today at 4pm CET/10am EST. To attend the call and Q&A session, [please click here](#). A replay will be made available on the investors section of the Hyloris website shortly after the call.

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### **About Hyloris Pharmaceuticals SA**

Based in Liège, Belgium, Hyloris is an innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals. Hyloris develops proprietary products it believes offer significant advantages compared to currently available alternatives, with the aim to address the underserved medical needs of patients, hospitals, physicians, payors and other stakeholders in the healthcare system. Hyloris currently has two early commercial-stage products, Sotalol IV for the treatment of atrial fibrillation, commercialised through its partner AltaThera, and Maxigesic® IV, a non-opioid analgesic product for the treatment of pain, developed with the Company's partner, AFT Pharmaceuticals. Additionally, Hyloris has 12 product candidates in various stages of development across the Company's wider portfolio with a focus on intravenous cardiovascular drugs and other potential high value reformulations. Read more at [www.hyloris.com](http://www.hyloris.com). Hyloris stands for "high yield, lower risk" and 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.



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**About Purna Pharmaceuticals NV**

Purna Pharmaceuticals is a family-owned Belgian company specialized in development and manufacturing of pharmaceutical products. Having expertise in all aspects of development and manufacturing, Purna Pharmaceuticals can take innovative ideas or technologies from early development to industrial manufacturing of finished product. Over the years, Purna Pharmaceuticals has established a reputation of excellence and a global presence in the pharma industry, resulting in the status of preferred partner for most of the top-10 pharma multinationals.

**About Creafund NV**

Creafund is an evergreen holding that invests for the long-term, specialised in buyout and growth capital for mid-sized companies. It was founded in 2001, has backed over 30 companies since its inception and currently has €200 million assets under management. It is co-owned by its management and 50 Flemish entrepreneur-families, who mobilise their network, experience, equity and common sense. Creafund has partnered with Purna Pharmaceuticals since 2003, providing active and solid support in co-operation with Purna's dynamic management and its ambitious plans.

**Forward-looking statements**

Certain statements in this press release are "forward-looking statements." These forward-looking statements can be identified by the use of 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.

