Hyloris announces US FDA approval for Podofilox Gel

- Product previously referenced as HY-016, targeting genital and perianal warts
  - US Commercialization by partner Padagis to start in December 2023
    - Second U.S. market approval of the year after Maxigesic® IV

Liège, Belgium – 04 December 2023 – 7AM 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 that its partner Padagis US LLC has received final approval from the United States Food & Drug Administration (FDA) on its abbreviated New Drug Application (ANDA) for Podofilox Gel, the first drug product generic to Condylox Gel 0.5%® in the U.S.

Podofilox Gel is an antimycotic drug for the topical treatment of external genital and perianal warts.

For the 12 months period ending December 2022, Condylox® Gel 0.5% had U.S. sales of approximately $9 million according to IQVIA Health. The FDA has granted Competitive Generic Therapy (CGT) exclusivity providing Padagis with a 180 day market exclusivity period during which other generics may not be launched. Commercialization by Padagis will commence in December 2023.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"This is the second product approval of the year in the U.S. supported by Hyloris, following our recent success with Maxigesic® IV. We are excited to launch, with Padagis, the first generic version of Condylox® Gel in the US. The availability of the generic Condylox® Gel reinforces Hyloris' mission to make a meaningful difference in the lives of patients by delivering innovative and accessible pharmaceutical solutions. The company remains focused on expanding its portfolio to address unmet medical needs and contribute to a more sustainable healthcare system."*

About genital and perianal warts

Genital and perianal warts are caused by certain types of the Human Papilloma Virus (HPV), the most common sexually transmitted disease. Genital HPV infections have an estimated prevalence of 10% to 20% and remain mostly asymptomatic. Around 1% of the sexually active population in the U.S. presents with the most visible manifestation of genital HPV infections, genital or perianal warts[1]. Patients affected by genital warts can experience itching, bleeding and mucus discharge.

A vaccine for HPV exists, but a cure does not[2].

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 1 approved high barrier generics product launched in the U.S. and 2 high barrier generic products in development.

[1] Human Papillomavirus: Clinical Manifestations and Prevention | AAFP
[2] Genital Warts - StatPearls - NCBI Bookshelf (nih.gov)

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.

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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.