Hyloris Announces Earlier than Expected PDUFA Date for Maxigesic® IV

PDUFA date set on 30 June 2022, ahead of the August to September 2022 timeframe initially expected

Liège, Belgium – 15 November 2021, 7:00 am CET – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that the U.S. Food and Drug Administration (FDA) has set the Prescription Drug User Fee Act date (PDUFA) for the New Drug Application (NDA) for Maxigesic® IV on 30 June 2022. The PDUFA date is the date by which the FDA must respond to an NDA.

Maxigesic IV is a novel, unique combination of 1000mg paracetamol and 300mg ibuprofen solution for infusion, indicated for the relief of mild to moderate pain and for the management of moderate to severe pain as an adjunct to opioid analgesics, where an intravenous route of administration is considered clinically necessary. Maxigesic IV has been developed under the collaboration agreement between Hyloris and AFT Pharmaceuticals and is currently licensed in over 100 countries across the globe, has been registered in 28 countries and is now launched in 5 countries. Maxigesic IV is protected by several granted patents and pending patent applications.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*We are extremely pleased that the PDUFA date comes earlier than expected, which offers the potential for earlier registration and commercialisation in the U.S. Together with our partners, we are looking forward to working with the FDA during the review process and to further executing on our global commercial rollout. Upon approval in the U.S., Maxigesic IV will be commercialised by Hikma Pharmaceuticals, a leading supplier of complex, injectable hospital products in the U.S.*"

The NDA for Maxigesic IV was based on positive data from two Phase 3 studies of Maxigesic IV: i) a randomised, double-blind, placebo-controlled efficacy trial in 276 patients following bunionectomy surgery; and ii) an open-label, multi-centre, single arm, multiple dose safety study in 232 patients undergoing general, orthopaedic, or plastic surgery. As previously reported, treatment with Maxigesic IV was well-tolerated, had a faster onset of action and offered higher pain relief compared to ibuprofen IV or paracetamol IV alone in the same doses. Moreover, the superior analgesic effect of Maxigesic IV was supported by a range of secondary endpoints, including reduced opioid usage rates compared to the paracetamol IV, ibuprofen IV, and placebo treatment groups ($P \leq 0.005$)[1]. The open-label Phase 3 safety study demonstrated that Maxigesic IV, administered 6-hourly as a 15-minute infusion over an exposure period of 48 hours to 5 days, was safe and well-tolerated, and was perceived positively by study participants, supporting a favourable risk benefit profile.[2]

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 14 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,

[1] Daniels *et al*, 2019, Clinical Therapeutics
[2] Gottlieb *et al*, 2021, Biomedicine & Pharmacotherapy

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 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.