Hyloris Announces FDA Acceptance of New Drug Application for Maxigesic® IV in Post-Operative Pain

Hyloris to receive $1 million milestone payment

Maxigesic® IV has the potential to combat the opioid crisis in the U.S.

Liège, Belgium – 1 November 2021 – 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 accepted the New Drug Application (NDA) for Maxigesic® IV, a novel, unique combination of 1000mg paracetamol and 300mg ibuprofen solution for infusion, for the treatment of post-operative pain. In addition, the Company informs that the US Patent and Trademark Office (USPTO) has issued a Notice of Allowance and granted the process and formulation patents of Maxigesic IV in the U.S. The patents are expected to be issued early 2022 after completion of the final administrative requirements.[1]

The FDA is expected to confirm the Prescription Drug User Fee Act (PDUFA) action date for the filing in due course. The PDUFA date – the date at which the FDA must respond to the application – will be notified later this year, and is estimated to be between August and September 2022.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*The NDA acceptance marks an important milestone for our company, and is a major step toward bringing much needed innovation in non-opioid, post-operative pain management and addressing the current opioid crisis, which is responsible for many deaths in the U.S. each year. Together with our partners, we are looking forward to working with the FDA and to further executing on our global commercial rollout. Upon approval, Maxigesic IV will be commercialised by Hikma Pharmaceuticals, a leading supplier of complex, injectable hospital products in the U.S.*"

The NDA submission is 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 ($P \leq 0.005$)[2]. 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.[3]

Maxigesic IV has been developed under the collaboration agreement signed in 2012 between Hyloris and AFT Pharmaceuticals. The product 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.

[1] https://portal.uspto.gov/pair/PublicPair (application number 15/326958)
[2] Daniels *et al*, 2019, Clinical Therapeutics
[3] Gottlieb *et al*, 2021, Biomedicine & Pharmacotherapy

About Post-Operative Pain Management

Globally, approximately 1.2 billion vials are sold per year in the non-opioid IV analgesic space, of which >260 million vials of IV paracetamol that represent a global market of >$700 million.[4] In 2019, 51 million surgical procedures were performed in the U.S. and the overall treatment of post-operative pain has not substantially improved over the past 20 years, with the misuse of opioids remaining a key public health issue. Recently released data by the Centers for Disease Control and Prevention (CDC) show that drug overdose deaths reached a record high of 93,331 in 2020, of which 57,550 (62%) were due to synthetic opioid misuse. This represented a significant increase as compared to 2015 where synthetic opioids were involved in 18% of all overdose deaths. The CDC estimate that the total economic burden of prescription opioid misuse in the U.S. alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

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 13 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, 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.

[4] IQVIA