# Hyloris announces U.S. FDA Approval of Maxigesic® IV

- Maxigesic® IV a potent non-opioid painkiller, to be marketed in the U.S. under the tradename Combogesic® IV
- First U.S. sales expected in early 2024, triggering a milestone payment of USD 2,1 million

**Liège, Belgium – 18 OCTOBER 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 Maxigesic® IV has been approved for the relief of mild to moderate pain and for the management of moderate to severe pain as an adjunct to opioid analgesics in adults, where an intravenous route of administration is considered clinically necessary.

The approval for the New Drug Application (NDA) is based on positive data from a Phase 3 program in which Maxigesic® IV demonstrated that it was well tolerated and offered faster onset of action and higher pain relief compared to Paracetamol IV (Acetaminophen IV) and Ibuprofen IV, as well as placebo. The superior analgesic effect of Maxigesic® IV was also supported by a range of secondary endpoints, including reduced opioid usage rates.

***Stijn Van Rompay, Chief Executive Officer of Hyloris, commented:*** *"I'm exceptionally proud of what the team at Hyloris achieved, together with our development partner AFT Pharmaceuticals."*

*"Bringing innovation by reformulating existing medicines highlights how Hyloris can improve patient outcomes, specifically by addressing the devastating opioid crisis in the biggest health care market in the world."*

*"Maxigesic® IV demonstrates the potential of our strategy of bringing product candidates to market within our strict criteria: a development of 7 years or less, and R&D costs averaging less than EUR 7 million.[1]"*

An exclusive license and distribution agreement for the U.S., was already signed between Hyloris' partner AFT Pharmaceuticals ("AFT") and Hikma Pharmaceuticals ("Hikma"). Under the terms of the development collaboration agreement between Hyloris and AFT, Hyloris is eligible to receive a share

[1] Not adjusted for inflation and exchange rate differences

on any product-related revenues, such as license fees, royalties and milestone payments, received by AFT.

Distribution of Maxigesic® IV in U.S. hospitals should start in early 2024. Following first U.S. sales, Hyloris will be entitled to a milestone payment of USD 2,1 million. In addition, the payment of USD 1,5 million (approximately EUR 1,4 million) relating to existing trade receivables is expected.

**About the opioid pandemic in the U.S.**

The development of chronic opioid use after surgery is one of the most common post-operative complications[2] with particularly devastating consequences. In the U.S., prevalence of new chronic opioid use after surgical procedures was estimated close to 6%[3].

In the past 2 decades, prescription opioid usage in the U.S. contributed to over 600,000 deaths related to opioid overdoses, with the annual death toll rising tenfold between 1999 and 2021 (80,000 deaths in 2021). Nearly 17,000 deaths involved prescription opioids in 2021[4].

Patients requiring medical attention related to opioid abuse account for around $11 billion of added costs to the U.S. healthcare system annually, or 1% of all hospital costs[5].

**About post-operative pain**

Post-operative pain is a normal response to surgical intervention and is a cause of delayed recovery and discharge after surgery.

The global post-operative pain therapeutics market reached a value of USD 12.6 billion in 2023[6] and is anticipated to grow at a CAGR of 4.7% to reach a value of USD 19 billion by 2032, with the U.S. as the largest market.

Approximately 50 million surgeries are performed in the U.S.[7] annually. Pain relief after surgery continues to be a major medical challenge with more than 80% of patients reporting acute postoperative pain[8]. Medical professionals are increasingly aware of the societal impact of opioid

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7990836/
[3] https://jamanetwork.com/journals/jamasurgery/fullarticle/2618383
[4] Opioid Data Analysis and Resources | Opioids | CDC
[5] Premier | Opioid Overdoses Costing U.S. Hospitals an Estimated $11… (premierinc.com)
[6] https://www.researchandmarkets.com/reports/5805706/global-postoperative-pain-therapeutics-market
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7388795
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5626380/

abuse, as evidenced by the decrease in opioid prescriptions over the last decade in the U.S.[9], adding to the need for potent non-opioid alternatives.

**About Maxigesic® IV**

Maxigesic® IV is a unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion for use post-operatively. Results from a randomised, double-blind, placebo-controlled Phase 3 trial in 276 patients following bunion surgery demonstrated that Maxigesic® IV was well-tolerated and 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 consumption compared to the Paracetamol IV and Ibuprofen IV treatment groups (p-value < 0.005)[10]. Hyloris holds several patents for the U.S. market, with the latest expiring in 2038.

Maxigesic® IV is, to date, licensed in over 100 countries, approved in over 40 countries and marketed in over 20 countries.

**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 3 high barrier generic products in development.

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.

[9] https://www.ama-assn.org/press-center/press-releases/report-shows-decreases-opioid-prescribing-increase-overdoses
[10] Daniels et al, 2019, Clinical Therapeutics

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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.