Hyloris Announces Launch of Maxigesic® IV in the U.S. and approval In Canada

- Maxigesic® IV, a Potent Non-opioid Painkiller, Marketed in the U.S. under the Tradename Combogesic® IV
- Maxigesic® IV approved in Canada

Liège, Belgium – 27 February 2024, 06:00 PM CET – Non-regulated information – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that Hikma Pharmaceuticals (Hikma) has launched Maxigesic® IV in the U.S. under the tradename Combogesic® IV.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"I am delighted with the rapid marketing launch by our partner Hikma Pharmaceuticals, a leading supplier of injectable medicines globally. The initial feedback from the market is encouraging. Combogesic® IV represents a significant innovation in pain management, offers effective pain relief and importantly provides clinicians a valuable alternative to opioid analgesics."*

Hyloris is entitled to a milestone payment of USD 1,1 million, in addition to the USD 1 million that became due upon product manufacturing, which occurred in December 2023.

Approval of Maxigesic® IV in Canada

Maxigesic® IV has recently been granted marketing authorization by Health Canada.

Canada[1] is facing a significant public health crisis related to opioid use with debilitating consequences for individuals, families, and communities. 22 Canadians die on average each day from apparent opioid toxicity. Between 2022 and 2023, health systems have seen an 11% year over year increase in the number of opioid-related hospitalizations. Beyond the human toll, the opioid crisis has significantly impacted Canada's economy, costing an estimated CAD 3,5 billion across healthcare, law enforcement, and lost productivity.

Stijn Van Rompay added: *"When launched, it will fill the critical need for post-surgical pain management between inadequate non-steroidal anti-inflammatory drugs (NSAIDs) and habit-forming opioids."*

About the opioid pandemic in the U.S.

The opioid pandemic in the U.S. is a critical healthcare issue, with chronic opioid use after surgery being one of the most common post-operative complications[2]. The devastating consequences are reflected in the prevalence of new chronic opioid use post-surgery in the U.S. 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. In 2021 alone approximately 80,000 deaths were attributed to opioid overdoses, with nearly involving prescription opioids. The economic impact is also

[1] https://health-infobase.canada.ca/substance-related-harms/opioids-stimulants/
https://pubmed.ncbi.nlm.nih.gov/33279425/

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7990836/ https://jamanetwork.com/journals/jamasurgery/fullarticle/2618383
Opioid Data Analysis and Resources | Opioids | CDC
Premier | Opioid Overdoses Costing U.S. Hospitals an Estimated $11… (premierinc.com)

substantial, as patients requiring medical attention related to opioid abuse contribute around USD 11 billion in added costs to the U.S. healthcare system annually, constituting 1% of all hospital costs.

About Maxigesic® IV

Maxigesic® IV is a unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion (in a 100 ml bottle) 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). 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 Pharmaceuticals SA

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.

The Company's development strategy primarily focuses on leveraging established regulatory pathways, such as the FDA's 505(b)2 pathway in the U.S or equivalent regulatory frameworks in other regions which are specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This approach can reduce the clinical burden required for market entry, and significantly shorten the development timelines, leading to reduced costs and risks.

Hyloris has built a broad, patented portfolio of 18 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over existing alternatives. Two products are currently in early phases of commercialization in collaboration with commercial partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. In addition to its core strategic focus, the Company has 1 approved high barrier generic product launched in the U.S. and 2 high barrier generic products in development.

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.