Press Release
Regulated Information

Hyloris Announces Major Commercial Partnership in the U.S. for Maxigesic® IV

Hikma Pharmaceuticals, a leading supplier of complex, injectable hospital products in the U.S., to commercialise Maxigesic IV in the U.S.

Hyloris is eligible to receive $4 million in regulatory based milestones as well as commercial milestones and a share of net profit

Maxigesic IV has potential to combat the opioid epidemic in pain management

Liège, Belgium – 28 April 2021 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to bringing innovative treatments that offer added value to underserved patient populations, today announces that its partner for Maxigesic IV, AFT Pharmaceuticals ("AFT"), has signed an exclusive license and distribution agreement with Hikma Pharmaceuticals ("Hikma") for the U.S. commercialisation of Maxigesic IV, a novel, patented, non-opioid treatment for post-operative pain.

Under the terms of the agreement with AFT, Hikma will have exclusive rights for the sales, marketing, and distribution of Maxigesic IV in the U.S. Hyloris is eligible to receive $4 million in regulatory based milestones as well as commercial milestones plus a share of any additional product-related income received by AFT in the U.S.

Hikma (LSE: HIK.L) is a global pharma company focused on complex and differentiated branded generics and generic pharmaceuticals and is a leading supplier of injectable hospital products in the U.S. across a broad range of indications, including respiratory, oncology and pain management. The Company generated group revenue of $2.34Bn in 2020.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*This partnership marks a major milestone for Hyloris and represents an important step forward in bringing much needed innovation in post-operative pain management to patients and physicians in the U.S. Hikma's large U.S. footprint, their scale, network and business values make them an ideal partner for the successful rollout of Maxigesic IV in the U.S. The misuse of and addiction to opioids is a major public health issue with nearly 50,000 deaths annually in the U.S. due to opioid-involved overdoses. There is an urgent need for safer and more effective non-opioid pain treatments in the post-operative hospital setting, and thanks to its unique, dual mode-of-action, Maxigesic IV has the potential to become a valuable pain treatment option without the side effects and risk of addiction associated with opioids.*"

Globally, approximately 1.2 billion vials[1] are sold per year in the non-opioid analgesic space and the market for post-operative pain is growing rapidly and is forecasted to reach $1.7 billion in 2028 in the U.S., up from $745 million in 2019[2]. 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. The Centers for Disease Control and Prevention 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.

[1] IQVIA
[2] DelveInsight Market Research Report (2020)

About Maxigesic® IV

Maxigesic IV has been developed under the development collaboration agreement signed in 2012 between Hyloris and AFT Pharmaceuticals, and is to date, licensed in >90 countries, approved in 20 countries and marketed in three countries. 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 ($P<0.005$)[3]. An additional exposure study has demonstrated Maxigesic IV's efficacy and safety in an expanded population group over a longer treatment period[4]. Maxigesic IV is protected by several granted and pending patent applications. The preparations to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) by AFT are progressing well.

About Hyloris Pharmaceuticals

Hyloris is a specialty biopharma company identifying and unlocking hidden potential in existing medications for the benefit of patients and the healthcare system. Hyloris applies its knowhow and technological innovations to existing pharmaceuticals and has built a broad proprietary product pipeline that has the potential to offer significant advantages over currently available alternatives. Hyloris currently has two partnered, commercial-stage products: 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.

For more information, please contact Hyloris Pharmaceuticals:

Marieke Vermeersch
VP Investor Relations and Corporate Communications
M: +32 (0)479 490 603
marieke.vermeersch@hyloris.com

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.

[3] Daniels *et al*, 2019, Clinical Therapeutics
[4] Maxigesic IV Phase 3 exposure study. Study ID No AFT-MXIV-11. NCT04005755. Submitted for publication