Press Release
Regulated Information

Hyloris Announces Extension of Footprint of Maxigesic® IV into South America

Broadening of the addressable market for Maxigesic IV in Latin America and the Caribbean to 17 countries

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

Liège, Belgium – 6 May 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 extended its existing license and distribution agreement with Pharma Bavaria International for the commercialisation of Maxigesic IV, a novel, patented, non-opioid treatment for post-operative pain, in South America.

The extended collaboration further builds on the agreement signed with Pharma Bavaria in February 2020 for the commercialisation of Maxigesic IV in 12 countries in Central America. Following multiple licensing deals with strong local players over the past 12 months, Maxigesic IV is now licensed in >100 countries across the globe, including the major markets in Europe and the U.S. The focus over the next 24 months will now shift towards accelerating regulatory submissions and launches in these territories.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*We are pleased that AFT has extended its existing agreement with Pharma Bavaria, a strong international player that promotes and distributes innovative pharmaceuticals in >45 countries, with focus on major growth regions and emerging economies, and an existing portfolio of hospital-based injectable pain medications. Today's news further demonstrates the urgent need for safer and more effective non-opioid pain treatments in the post-operative hospital setting, and the potential of Maxigesic IV to address that need.*"

Globally, approximately 1.2 billion vials[1] are sold per year in the non-opioid analgesic space and the market for pain medicines in Latin America is expected to grow at an average annual rate of 3.5% until 2027.[2]

About Maxigesic® IV

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

[1] IQVIA
[2] Research and Markets 2020
[3] Daniels *et al*, 2019, Clinical Therapeutics

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.

[4] Maxigesic IV Phase 3 study. Study ID No AFT-MXIV-11. NCT04005755. Submitted for publication