Press Release

Hyloris' Partner AFT Pharmaceuticals Signs Licensing Agreement with Aguettant for Maxigesic® IV in Eight European Markets

Footprint across Europe now extended to a total of 20 EU member states

Maxigesic® IV offers a non-opioid alternative in post-operative pain management

Liège, Belgium – 5 March 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 AFT Pharmaceuticals ("AFT") has signed an exclusive licensing agreement with Aguettant for Maxigesic IV, a novel, dual mode-of-action non-opioid pain treatment delivered through intravenous (IV) infusion, in eight European markets.

The agreement with Aguettant means that Maxigesic IV is now licensed in 20 out of the 27 EU member states (including the major pharma markets in the EU: Germany, France, Italy, and Spain) as well as the UK. Aguettant gains the exclusive rights to Maxigesic IV in the Nordics (Finland, Norway, Denmark, Sweden and Iceland), Spain, Portugal, and the Netherlands. AFT expects sales of Maxigesic IV in these territories to commence in early 2022.

The market for post-operative pain is growing rapidly and is forecasted to reach $553 million in 2028 across the five major markets in Europe (up from $178 million in 2019)[1].

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*We are very pleased that AFT has entered into a licensing agreement with Aguettant, a major player in injectable pharmaceutical specialities and a strong sales record in the hospital sector across the EU. This agreement extends Maxigesic IV's footprint in Europe and significantly expands its addressable market. There is an increasing 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.*"

Maxigesic IV is a novel, dual mode-of-action, non-opioid pain treatment for use post-operatively in hospitals when patients cannot take a medicine orally. It is a unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion, thereby reducing both pain and inflammation. Results from a randomised, placebo-controlled Phase 3 trial demonstrated that Maxigesic IV was well-tolerated and had a faster onset of action, offered higher pain relief, and provided the potential to reduce the use of opioids compared to ibuprofen IV or acetaminophen IV alone in the same doses[2]. Further exposure studies have demonstrated the drug's efficacy and safety in an expanded population group over a longer treatment period[3]. Hyloris and AFT signed a development collaboration agreement in 2012 for Maxigesic IV and AFT has now licensed the product to partners covering more than 90 countries. Maxigesic IV is protected by several granted and pending patent applications. Under the terms of the development collaboration agreement between Hyloris and AFT, Hyloris is eligible to receive a share on any product-related revenues, such as license fees, royalties, milestone payments, received by AFT.

[1] DelveInsight Market Research Report (2020)
[2] Daniels *et al*, 2018, Clinical Therapeutics
[3] Maxigesic IV Phase 3 exposure study. Study ID No AFT-MXIV-11. NCT04005755. Results presently unpublished

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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 analgesic for the treatment of pain. 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 has 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 at https://www.linkedin.com/company/hyloris-pharmaceuticals.

Disclaimer and forward-looking statements

Hyloris stands for "high yield, lower risk" and 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.