Hyloris Announces Launch of Maxigesic® IV, a Novel Non-Opioid Pain Treatment, in Key European Markets

Marks first European launches of Maxigesic IV, a well-tolerated and effective non-opioid pain treatment

Liège, Belgium – 8 July 2021 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that Maxigesic IV is now available in Germany, the largest European pharmaceutical market, and Austria.

Maxigesic IV is a novel, patented, non-opioid treatment for post-operative pain and is a unique combination of 1000mg paracetamol and 300mg ibuprofen solution for infusion. Hyloris' partner AFT Pharmaceuticals works together with distribution partners with strong local presence to commercialise the product globally.

Maxigesic IV is currently licensed in more than 100 countries across the globe, and it has been registered in 24 countries. Following the launch in Germany and Austria, the product is now available in 5 countries: Australia, New Zealand, The United Arab Emirates, Germany, and Austria.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*We are pleased that AFT and its partner Ever Pharma have now launched Maxigesic IV in Germany and Austria. We are convinced that Ever Pharma is the ideal partner to make this valuable new non-addictive pain treatment available to patients in Germany and Austria given their strong footprint in key European markets, and their expertise with complex injectables in multiple therapeutic areas, including anaesthesia. We look forward to continuing to update the market as we, and our partner AFT, make further progress in the regulatory activities, launches and further roll-out of Maxigesic IV across the globe.*"

Annually, over 5.2 million surgical procedures are performed in Germany, and the market for postoperative pain in Germany is expected to grow to $166.5 million by 2028 at a CAGR of 11.58% from 2017-2028.[1]

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 and 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 ($P<0.005$).[2] In addition, the safety and tolerability of repeated doses of Maxigesic IV over an extended period was assessed in an open-label, multi-centre, single arm study in 232 patients undergoing orthopaedic or plastic surgery. This extension study demonstrated that Maxigesic IV, administered 6-hourly as a 15-minute infusion between 48 hours to 5 days was safe and well-tolerated, and was

[1] Postoperative Pain Market Insights, Epidemiology and Market Forecast – 2028. DELVEINSIGHT
[2] Daniels *et al*, 2019, Clinical Therapeutics

perceived positively by study participants, supporting a favourable risk benefit profile.[3] Under the terms of the collaboration agreement with AFT, Hyloris is eligible to a high minority share of Maxigesic IV related income generated by AFT, excluding income generated in Australia and New Zealand.

About Hyloris Pharmaceuticals

Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimising 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 13 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Two products are currently commercialised 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.

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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.

[3] Gottlieb *et al*, 2021, Biomedicine & Pharmacotherapy