Hyloris Announces Approval of Maxigesic® IV in the UK and Ireland

Maxigesic® IV provides a non-opioid, dual mode-of-action pain management alternative to traditional analgesics

Liège, Belgium – 19 October 2021 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces further extension of the European footprint of Maxigesic® IV, a novel, unique combination of 1000mg paracetamol and 300mg ibuprofen solution for infusion, for the treatment of post-operative pain.

Maxigesic IV has now obtained regulatory approvals in the UK and Ireland, thereby increasing the number of countries in which Hyloris' partner AFT Pharmaceuticals obtained regulatory approval for Maxigesic IV to 27 countries, from 21 countries at the end of March 2021. Kensington Pharmaceuticals Ltd., the distributor for the UK, and Jed Pharma Ltd, the distributor in Ireland, are now gearing up to commence sales in the first quarter of 2022.

Annually, over 3.1 million surgical procedures are performed in the UK and Ireland, and the market for postoperative pain in these countries is expected to grow to $122.1 million by 2028 at a CAGR of 13.23% from 2017-2028.[1]

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*Maxigesic IV is a breakthrough non-opioid pain treatment, offering surgeons a well-tolerated and effective alternative to highly addictive opioids. We are very pleased that Maxigesic IV is gaining further momentum with additional regulatory approvals and together with our partners, we look forward to making the product available in these key markets.*"

Maxigesic IV has been developed under the collaboration agreement signed in 2012 between Hyloris and AFT Pharmaceuticals. The product is currently licensed in over 100 countries across the globe, has been registered in 27 countries and is now launched in 5 countries. Maxigesic IV is protected by several granted patents and pending patent applications.

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. Outside of its core strategic focus, the Company also has 3 high barrier generic products in development and registration phase. Two products are currently in initial phases of commercialisation 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.

[1] Postoperative Pain Market Insights, Epidemiology and Market Forecast – 2028 - DelveInsight

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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.