Hyloris Announces Further Extension of Maxigesic® IV Footprint

Regulatory approvals in South Korea, the fourth largest pharma market in Asia, and Panama

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

Liège, Belgium – 21 September 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 global 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 South Korea, the fourth largest pharmaceutical market in Asia, and Panama, thereby increasing the number of countries in which Hyloris' partner AFT Pharmaceuticals obtained regulatory approval for Maxigesic IV to 26 countries, from 24 countries at the end of March 2021.

Kyongbo Pharmaceuticals Co., the licensee for the South Korean market, is now gearing up to commence sales in early 2022. The licensee for Panama, Pharma Bavaria International, which has a license agreement for Maxigesic IV in 17 countries in Latin, Central America, and the Caribbean, is planning to launch the product later this year in Panama. The commercial rollouts represent the first launches of Maxigesic IV in Asia and Latin America.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*Maxigesic IV is a breakthrough non-opioid post-operative pain treatment, offering clinicians a well-tolerated and effective alternative to highly addictive opioids. We are very pleased that Maxigesic IV is gaining further international momentum with additional regulatory approvals in key markets. Meanwhile, we and our partners are also making good progress with the regulatory submission process in the U.S., and we look forward to updating the market on further achievements over the next period.*"

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 26 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 products that have the potential to offer significant advantages over currently 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.