Press release
Non-regulated Information

Hyloris announces potential registration date for Maxigesic® IV in the US

- PDUFA goal date set for 17 October 2023 by U.S. Food & Drug Administration
- Exclusive commercial partner for Maxigesic® IV in the U.S. is Hikma Pharmaceuticals, a leading supplier of complex, injectable hospital products

Liège, Belgium – 2 May 2023 – 7AM CET – Non-regulated information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces the US Food & Drug Administration has set 17 October 2023 as the date by which it expects to respond to the application regarding Maxigesic® IV.

The US regulatory body confirmed it has received a complete response in relation to its questions on extractables and leachables from Maxigesic® IV's primary packaging – the glass vial and the stopper in which the drug product is stored. The FDA requested additional data in July 2022.

Hyloris' partner AFT Pharmaceuticals ("AFT") submitted the additional data to the FDA on 17 April 2023. The Prescription Drug User Fee Act (PDUFA) goal date of 17 October 2023 set by the FDA confirms the anticipated review period of 6 months, and a potential registration of Maxigesic® IV for the US market before the end of 2023.

Sales could follow soon after, with an exclusive license and distribution agreement already signed between AFT and Hikma Pharmaceuticals ("Hikma"). Hikma is a leading supplier of complex, injectable hospital products in the U.S.

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.

About Maxigesic® IV

Maxigesic® IV is a novel, dual mode-of-action, non-opioid pain treatment for use post-operatively in hospitals or when patients cannot take 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 randomized, 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 paracetamol IV alone in the same doses. Further exposure studies have demonstrated the drug's efficacy and safety in an expanded population group over a longer treatment period. Maxigesic® IV is protected by several granted and pending patent applications.

About Hyloris Pharmaceuticals

Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimizing 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 16 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.

Two products are currently in initial phases of commercialization 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 Company 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.