Press release
Non-regulated Information

Hyloris announces commercial partnership for Maxigesic® IV in 9 European countries

- Exclusive licensing and distribution agreement signed with Salus Pharmaceuticals in Lithuania, Estonia, Latvia, Croatia, Slovenia, Serbia, North Macedonia, Montenegro and Bosnia
- First commercial launches planned later this year

Liège, Belgium – 24 January 2023 – 7AM CET – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that its partner AFT Pharmaceuticals ("AFT") has signed an exclusive licensing and distribution agreement with Salus Pharmaceuticals for Maxigesic® IV, a novel, dual mode-of-action non-opioid pain treatment delivered through intravenous (IV) infusion, in 9 European markets.

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.

The agreement with Salus Pharmaceuticals encompasses the following European territories: Lithuania, Estonia, Latvia, Croatia, Slovenia, Serbia, North Macedonia, Montenegro, and Bosnia.

Maxigesic® IV is already registered in Lithuania, Estonia, Latvia, Croatia and Slovenia, where the first commercial launches are expected later this year. Registration applications will be filed in the remaining countries (Serbia, North Macedonia, Montenegro, Bosnia).

Last November Maxigesic® IV was launched France and Italy, together with Ever Pharma GmbH.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "*We are pleased with Maxigesic® IV's further roll-out. This novel non-opioid pain treatment can soon offer relief to patients in even more countries across Europe, and underlines the attractiveness of our business model of reformulating and repurposing existing medicinal products, including its ability to provide significant benefits to patients and health care providers.*"

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 SA

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 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 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 https://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.