

Hyloris Announces Expansion of Maxigesic® IV into Brazil

- Exclusive licensing and distribution agreement with Halex Istar for Maxigesic® IV in Brazil, South America's largest pharmaceutical market

Liège, Belgium – 18 July 2024 - 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 for Maxigesic® IV for Brazil with Halex Istar, a Brazilian pharmaceutical company specializing in injectable medications. This agreement will bring Maxigesic® IV, a novel, dual mode-of-action intravenous (IV) non-opioid pain treatment to South America's largest pharmaceutical market and a global top 10 market.

Hyloris CEO Stijn Van Rompay comments: "We are excited to partner with Halex Istar to bring Maxigesic® IV to Brazilian patients. Given the significant rise in prescription opioid use in Brazil¹, we believe this non-opioid pain treatment offers a much-needed alternative. Maxigesic® IV aligns perfectly with Halex Istar's expertise and market reach, and we are confident it will provide substantial benefits to both patients and healthcare providers".

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 unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion (in a 100 ml bottle) 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 -value < 0.005). Hyloris holds several patents for the U.S. market, with the latest expiring in 2038.

Maxigesic® IV has been co-developed with AFT Pharmaceuticals and is, to date, licensed in over 100 countries, approved in over 40 countries and marketed in over 20 countries.

¹ Bastos F, Krawczyk N. Reports of rising use of fentanyl in contemporary Brazil is of concern, but a US-like crisis may still be averted. *The Lancet Regional Health Americas*. 2023



About Hyloris Pharmaceuticals SA

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.

The Company's development strategy primarily focuses on leveraging established regulatory pathways, such as the FDA's 505(b)2 pathway in the U.S or equivalent regulatory frameworks in other regions which are specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This approach can reduce the clinical burden required for market entry, and significantly shorten the development timelines, leading to reduced costs and risks.

Hyloris has built a broad, patented portfolio of 18 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over existing alternatives. Two products are currently in early phases of commercialization in collaboration with commercial partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. In addition to its core strategic focus, the Company has 1 approved high barrier generic product launched in the U.S. and 2 high barrier generic products in development.

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



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