Press Release
Regulated Information

# Hyloris Announces Further Extension of European Footprint of Maxigesic® IV

Maxigesic IV, a novel non-opioid pain treatment, is now licensed in 22 EU member states

New agreements in Poland and Greece, which cover territories with a total population of >48.5 million people[1]

**Liège, Belgium – 8 April 2021 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL)**, a specialty biopharma company committed to bringing innovative treatments that offer added value to underserved patient populations, today announces that its partner AFT Pharmaceuticals ("AFT") has signed exclusive license and supply agreements with Mercapharm Sp.z.o.o ("Mercapharm") and Vianex SA ("Vianex") for the commercialisation of Maxigesic IV in Poland and Greece respectively.

Maxigesic IV is a novel, patented, non-opioid pain treatment administered through IV infusion, for use post-operatively in hospitals when patients cannot take a medicine orally.

The agreement with Mercapharm and Vianex further strengthens the European footprint of Maxigesic IV, which is now licensed in 22 out of the 27 EU member states (including the major pharma markets in the EU: Germany, France, Italy, and Spain) as well as the UK. AFT expects to receive regulatory approval in Poland and Greece in mid-2022, with sales expected to begin shortly thereafter.

**Stijn Van Rompay, Chief Executive Officer of Hyloris, commented:** "*We are pleased that AFT continues to successfully execute the international expansion strategy for Maxigesic IV through partnering with strong regional players that have excellent knowledge of the respective local hospital pharmaceutical markets. There is an urgent need for safer and more effective non-opioid pain treatments in the post-operative hospital setting, and thanks to its unique, dual mode-of-action, we believe that Maxigesic IV has the potential to become a valuable pain treatment option without the side effects and risk of addiction associated with opioids.*"

Maxigesic IV has been developed under the collaboration agreement signed in 2012 between Hyloris and AFT, and is to date, licensed in >90 countries, approved in 20 countries and marketed in three countries. Maxigesic IV is a unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion 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 (acetaminophen) 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 ($P<0.005$)[2]. An additional exposure study has demonstrated Maxigesic IV's efficacy and safety in an expanded population group over a longer treatment period[3]. Maxigesic IV is protected by several granted and pending patent applications. Under the terms of the collaboration agreement with AFT, Hyloris is eligible to receive a share on any product-related income, such as license fees, royalties, milestone payments or other net considerations, received by AFT.

[1] Worldbank Population Data 2019
[2] Daniels *et al*, 2019, Clinical Therapeutics
[3] Maxigesic IV Phase 3 exposure study. Study ID No AFT-MXIV-11. NCT04005755. Submitted for publication

**About Hyloris Pharmaceuticals**

Hyloris is a specialty biopharma company identifying and unlocking hidden potential in existing medications for the benefit of patients and the healthcare system. Hyloris applies its knowhow and technological innovations to existing pharmaceuticals and has built a broad proprietary product pipeline that has the potential to offer significant advantages over currently available alternatives. Hyloris currently has two partnered, commercial-stage products: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid analgesic for the treatment of pain. 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.

**For more information, please contact Hyloris Pharmaceuticals:**

Marieke Vermeersch
VP Investor Relations and Corporate Communications
M: +32 (0)479 490 603
marieke.vermeersch@hyloris.com

**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.