Hyloris Provides Additional Information on U.S. FDA Review of NDA Application for the Registration of Maxigesic IV®

- FDA did not report any issues with clinical data
- Hyloris is asked to submit a report describing potential extractable and leachable compounds expected to be present in the drug product based on the drug product packaging
- Hyloris is confident that it can deliver the requested information to FDA
- Hyloris is committed bringing Maxigesic IV to patients in the U.S. as soon as possible and continues to work with the FDA to support the application review

Liège, Belgium - 01 July 2022 – 8.00 PM CET - Regulated information - Inside Information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL) a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today provided additional details about the United States (U.S.) Food and Drug Administration (FDA)'s review of the New Drug Application (NDA) for the registration of Maxigesic IV®.

The FDA has informed Hyloris' development partner, AFT Pharmaceuticals, via a Complete Response Letter, that it was unable to complete its review of the NDA for Maxigesic IV® and has provided recommendations needed to address the application's deficiency. Importantly, the agency did not report any issues related to data generated during Maxigesic IV®'s clinical development program, and the deficiency is confined solely to the Quality section of the application dossier, and more specifically to revise a risk assessment of the required leachable compound study.

"We are corresponding with the FDA to address the recommendations highlighted in the letter as soon as possible," said **Stijn Van Rompay, Chief Executive Officer of Hyloris**. "*Hyloris initially submitted a toxicological risk assessment for all leachable compounds, however, we will need to re-submit this information based on confirmed compounds quantified using validated methods. As previously stated, this request required by the FDA falls well within the parameters of our normal operational budget and can be completed expeditiously, requiring no additional clinical data to be generated. Hyloris remains committed to Maxigesic IV®, and ensuring the product fulfills its commercial potential in the U.S. We will be updating the market on revisions to the U.S. commercialization timeline for this product candidate as we gain more clarity about the FDA's request*."

About Maxigesic® IV
Maxigesic IV has been developed under the development collaboration agreement signed in 2012 between Hyloris and AFT Pharmaceuticals, and is to date, licensed in more than 100 countries, approved in 39 countries and marketed in seven countries. Maxigesic® IV is a unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion for use post-operatively. The superior analgesic effect of Maxigesic IV demonstrated in a phase 3 trial was supported by a range of secondary endpoints, including reduced opioid consumption compared to the paracetamol IV and ibuprofen IV treatment groups ($P<0.005$). An additional exposure study demonstrated Maxigesic IV'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 14 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 4 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 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.