US FDA seeks more information on Maxigesic IV® application

For immediate release

Liège, Belgium – 01 July 2022 – Hyloris Pharmaceuticals SA (Euronext Brussels : HYL) announces that it has today received a Complete Response Letter (CRL) from the US Food and Drug Administration (FDA) on its application for the US registration of Maxigesic IV®. The FDA has only requested additional data on one remaining topic.

"We believe, along with our partners at AFT, that generating the additional information that FDA requires to support the NDA submission of Maxigesic IV® will allow the product to fulfill its full commercial potential in the US and not affect the Company's other existing development programs. The additional work required by FDA falls well within the parameters of our normal operational budget and will be completed expeditiously said **Stijn Van Rompay, Chief Executive Officer of Hyloris."**

Maxigesic® IV, is a novel, unique combination of 1000mg paracetamol and 300mg ibuprofen solution for infusion, for the treatment of post-operative pain and is currently licensed in more than 100 countries across the globe. It has also been registered in 39 countries and launched in 7 countries including Australia, Germany and Korea. The medicine is protected by several granted patents 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 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 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.