Press Release
Non-Regulated Information

Hyloris Announces U.S. FDA Approval for Tranexamic Acid Ready-to-Use (RTU)

- FDA Approval Obtained for the Abbreviated New Drug Application (ANDA) of Tranexamic Acid RTU
- U.S. Launch Expected in H2 2025

Liège, Belgium – June 3, 2025 – 06.00 PM CET – Non-Regulated Information - 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 Avenacy received U.S. FDA approval for its ANDA[1] of Tranexamic Acid Intravenous Premix Ready-to-Use (RTU) 10 mg/ml in a 100 ml vial.

Tranexamic Acid for injection is currently approved to reduce or prevent bleeding in hemophilia patients undergoing tooth extraction and is also widely used as a versatile hemostatic medication in a variety of clinical settings. The Premix RTU presentation eliminates the need for pre-administration dilution, offering a convenient, time-saving alternative that may streamline treatment and improve patient outcomes.

U.S. sales of intravenous tranexamic acid have grown significantly, reaching USD 29.1 million in the 12 months preceding March 2025.

Stijn Van Rompay and Thomas Jacobsen, Co-CEOs of Hyloris Pharmaceuticals, commented: “While ANDAs are not a core focus for Hyloris, this approval reflects our ability to execute. We look forward to its launch in the U.S. with our partner Avenacy in H2 2025."

Hyloris entered in 2024 into an exclusive U.S. licensing and supply agreement with Avenacy, a U.S. based specialty pharmaceutical company focused on critical injectable medications, for the commercialization of Tranexamic Acid RTU. The agreement is based on a profit-sharing structure between the parties.

[1] An ANDA (Abbreviated New Drug Application) is the FDA submission required to approve a generic drug

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.

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 22 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 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 undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

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