Press Release
Non-Regulated Information

Hyloris Announces Partnership for U.S Commercialisation of Tranexamic Acid Ready-to-Use (RTU)

- Exclusive licensing and supply agreement signed with Avenacy for the U.S. for Tranexamic Acid RTU
- Launch expected in 2025

Liège, Belgium – 26 December 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 it has signed an agreement with Avenacy for the exclusive commercialization of Tranexamic Acid Intravenous Ready-to-Use 10 mg/ml in a 100 ml vial for the U.S. An ANDA[1] has already been submitted to the U.S. Food and Drug Administration (FDA) by Hyloris with a decision anticipated in 2025.

Tranexamic Acid for injection is currently approved to reduce or prevent bleeding in hemophilia patients undergoing tooth extraction and is also used as a versatile hemostatic medication in various clinical settings. The RTU presentation eliminates the need for pre-administration dilution, streamlining treatment and potentially improving patient outcomes. U.S. sales of intravenous tranexamic acid have grown significantly and amounted to USD 29,7 million[2] in the 12 months before October 2024.

Co-CEO of Hyloris Pharmaceuticals Stijn Van Rompay commented: *"Avenacy, a specialty pharmaceutical company focused on critical injectable medications for diverse healthcare settings, is a strong partner for Hyloris. Their experience in commercializing injectable and RTU products aligns perfectly with bringing Tranexamic Acid RTU to U.S. hospitals and outpatient clinics."*

The partnership is based on a profit-sharing structure between the parties.

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 19 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over existing alternatives. Two

[1] A submission to the U.S. Food and Drug Administration (FDA) for approval of a generic drug
2 In the 12 months up to September 2024, 6,8 million doses were sold, with the RTU presentation accounting for 1,68 million doses (+25% compared to the same period in 2023). Source IQVIA.

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 (including Tranexamic Acid RTU).

Hyloris is based in Liège, Belgium. For more information, visit www.hyloris.com and follow-us on LinkedIn.

About Avenacy

Avenacy is a U.S.-based specialty pharmaceutical company, focused on supplying critical injectable medications used to treat patients in various medically supervised settings, from acute care hospitals to outpatient clinics and physician offices.

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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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