Hyloris Enrolls First Patient in Phase 3 Clinical Trial for its Proprietary Mouth Rinse to Control Incidences of Bleeding Related to Dental Procedures

- Innovative oral care solution aims to benefit patients taking blood thinning medications, who have an increased risk of prolonged bleeding during and after dental procedures
- Approximately 280 patients in the EU and U.S. will be randomized to receive either tranexamic acid oral solution or placebo
- Last patient out expected around end of 2024
- Study results expected first half of 2025

Liège, Belgium – February, 14 2024 – 6PM 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 the first patient has been enrolled in a pivotal Phase 3 clinical trial for Tranexamic Acid Oral Rinse.

Hyloris' product candidate is a new treatment for use in patients on anti-coagulant therapies (blood thinners) undergoing dental procedures with a risk of excessive bleeding. It is an oral solution containing the locally-acting antifibrinolytic agent tranexamic acid. Positive data in a Phase 1 pharmacokinetic (PK) trial in healthy subjects suggested the treatment was well tolerated under varied conditions with no serious adverse events following tooth extraction, while effectively controlling procedural bleeding without delaying clot formation. Data from this Phase 1 allowed Hyloris to define the optimal administration regimen for its proprietary oral solution for the current Phase 3 trial.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"Preventing bleeding with a convenient oral rinse to be self-administered at home, at work or in a dental office would improve patient outcomes after generally unpleasant tooth extraction procedures. The health care system is also served by shorter times to discharge and reducing the incidence of clinically relevant bleeding and thus the need for hospitalization."*

"Our proprietary mouth rinse demonstrates once again the opportunity that lies in reinventing existing medicines. We believe the potential for Tranexamic Acid Oral Rinse reaches even further than what is currently being tested, and we are exploring opportunities in broader related indications in patients undergoing oral surgical procedures with or without bleeding disorders that could benefit from a locally acting antifibrinolytic agent."

Close to 2 in 3 U.S. adults aged 18-64 visit dental professionals every year[1]. Around 8 million people in the U.S. take blood thinner medication[2]. A market study conducted by Hyloris indicated that more than 80% of U.S. based dental professionals would stock a locally acting tranexamic acid mouth rinse to use during and following relevant procedures such as tooth extractions.

Hyloris will seek regulatory approval in the United States first, before expanding to other territories. Conditional to a successful clinical study program, Hyloris expects to license the product candidate to a partner for commercialization in the U.S.

About this Phase 3 trial

This randomized, double-blind, multicenter, placebo-controlled Phase 3 trial is designed to demonstrate efficacy, safety and acceptability of the oral solution containing tranexamic acid to prevent possible oral haemorrhaging in patients treated with anticoagulants (blood thinners) and undergoing extraction of one or more teeth.

This study will measure and compare efficacy of the proprietary oral solution containing tranexamic acid against placebo in reducing the number of both clinically relevant and irrelevant bleeds in patients treated with anticoagulants and undergoing tooth extraction. Clinically relevant bleeds are defined as the need for medical attention or intervention.

An estimated 280 patients will be recruited at approximately 20 clinical sites across Europe and the United States. Eligible patients will be randomized to receive tranexamic acid oral solution or placebo for 7 days and followed for approximately one month. Recruitment is expected to be completed around the end of 2024 with final results available in the first half of 2025.

About Tranexamic Acid Oral Rinse

Hyloris' proprietary reformulated oral rinse was developed for use in minor surgical procedures with complications/bleedings. The formulation can be used by dental care professionals for patients on anti-coagulant therapies who benefit from the opportunity to continue their anti-coagulant treatments when scheduled for dental procedures. By addressing the unique challenges faced by

[1] https://www.cdc.gov/nchs/products/databriefs/db412.htm
[2] IBM Truven Health Analytics, 12 months ending December 31, 2018 for Commercial, Medicare and Medicaid patients (October 24, 2019)

individuals on blood thinners, this oral care solution seeks to enhance the overall dental experience and improve the oral health of these patients.

About Tranexamic Acid

Tranexamic acid is an antifibrinolytic agent that has been used for decades to reduce or prevent postoperative bleeding in patients with bleeding problems. The drug is currently approved for intravenous administration (CYKLOKAPRON® IV) in the U.S. for reduction or prevention of bleeding in patients having a high risk of intra and post-operative haemorrhage (during general and oral surgery, such as tooth extractions) due to a bleeding disorder such as haemophilia (as indicated). The drug is also approved in the U.S. as an oral tablet (LYSTEDA®) for cyclic heavy menstrual bleeding.

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 18 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 approved 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.