Hyloris Reports Positive Phase 1 Data for HY-004, a proprietary Tranexamic Acid Oral Mouth Rinse for bleeding related to dental procedures

- HY-004 provides a new treatment alternative for use in patients on anti-coagulant therapies undergoing dental procedures that have a risk of bleeding or complication
- HY-004 administered locally had minimal systemic exposure and was well-tolerated following molar extraction in healthy patients
- HY-004 to be developed to address a significantly larger target market
- Pivotal study expected to start early next year to usher HY-004 into later stage development

Regulated Information – Inside Information

Liège, Belgium - 20 July 2022 – 07:00 AM CEST - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announced positive results from a Phase 1 study of HY-004, an antifibrinolytic agent, tranexamic acid, as an oral mouth rinse proprietary formulation (Tranexamic Acid Oral Solution, 5%) in healthy patients following tooth extraction. HY-004 is being developed for use in patients on anti-coagulant therapies that are undergoing dental procedures with the potential for complications/bleeding. The study results showed that HY-004 was found to be well-tolerated under varied conditions with no serious adverse events following tooth extraction, while effectively controlling procedural bleeding without delaying clot formation. Hyloris also plans to investigate its use for broader related indications in patients undergoing oral surgical procedures with or without bleeding disorders that would benefit from a locally-acting antifibrinolytic agent.

"Tranexamic acid is an antifibrinolytic agent that has been used for decades intravenously to reduce or prevent postoperative bleeding in patients with bleeding problems, however, it has not been approved in a locally acting form to optimally enable coagulation following dental procedures", said **Stijn Van Rompay, Chief Executive Officer of Hyloris.** "Having a tranexamic acid oral rinse could serve the needs of more than 8 million[1][2] US people taking a blood thinner medication. Prevention of bleeding with a convenient oral rinse would help to improve both patient experience and healthcare outcomes, allowing shorter times to discharge and preventing hospitalization."

Mr. Van Rompay continued, "HY-004 is convenient to use, both in the office and at home. We conducted a market survey that indicated that more than 80% of US based dental professionals would stock a locally acting tranexamic acid mouth rinse like this to use following relevant procedures. We see a lot of potential in this product candidate since as an oral rinse, it provides efficient local activity. We believe that the opportunity for HY-004's potential use lies beyond tooth extraction and is not limited only to patients at risk of thromboembolic complications, which provides a very lucrative opportunity for Hyloris."

[1] IBM Truven Health Analytics, 12 months ending December 31, 2018 for Commercial, Medicare and Medicaid patients

[2] 65.5% of U.S. adults have a dental visit on annual basis - Products - Data Briefs - Number 412 - July 2021 (cdc.gov)

Mr. Van Rompay continued, “Based on these positive results in healthy patients that indicate our oral formulation was well-tolerated, we are planning to initiate a 12-month, 400-patient, pivotal study early next year.”

About HY-004

Hyloris HY-004 is a proprietary reformulated oral rinse 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.

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 hemorrhage (during general and oral surgery, such as tooth extractions) due to a bleeding disorder such as hemophilia (as indicated). The drug is also approved in the U.S. as an oral tablet (LYSTEDA®) for cyclic heavy menstrual bleeding.

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 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.