Hyloris Announces Positive Clinical Study Results for IV Aspirin

New Drug Application (NDA) will be Submitted to the U.S. Food & Drug Administration (FDA)

Liège, Belgium – 14 November 2025 – 07:00 AM CET – Regulated Information – Inside information – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), the specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announced positive topline results from the pivotal study in healthy participants evaluating its innovative and patent-protected intravenous (IV) aspirin formulation. The trial achieved all its targets, enabling progression towards submission of a New Drug Application (NDA) in 2026 and expected approval in 2027.

Oral aspirin is well established as the standard therapy for patients experiencing Acute Coronary Syndrome (ACS)[1], particularly those with myocardial infarction. Oral administration of aspirin can lead to delayed or incomplete platelet inhibition and is often challenging in case of emergency where patients are unconscious or have difficulties or are unable to swallow. The study showed that IV aspirin provides a much faster action compared to the same dose of oral aspirin, achieving peak platelet inhibition within two minutes of administration, whereas oral aspirin requires at least 30 minutes.

Hyloris' IV aspirin is designed to eliminate the risks of delayed, partial, or absent response associated with oral administration, ensuring immediate bioavailability and consistent platelet inhibition for all patients, especially those who are unconscious, sedated, intubated, have undergone defibrillation, or have difficulties or are otherwise unable to chew or swallow.

"*This innovative, patent-protected formulation reflects Hyloris' strategy of further optimizing established medicines to deliver fast, safe and predictable outcomes making a meaningful difference in hospital care. Intravenous aspirin formulation is currently not available in the United States. By unlocking aspirin's therapeutic potential, the IV formulation offers the fastest possible onset and high response regarding platelet inhibition. It provides a valuable option in acute and post-interventional antiplatelet therapy including cardiac and bypass surgery, where not only effective but also predictable and rapid platelet inhibition is essential, particularly in patients with increased platelet turnover or excessive platelet activation*", said Stijn van Rompay and Thomas Jacobsen, Co-Chief Executive Officers of Hyloris.

About aspirin and IV aspirin

Aspirin inhibits an enzyme responsible for producing substances involved in pain, inflammation, and blood clotting, thereby reducing inflammation and preventing platelets from sticking together. Oral aspirin is widely used at low doses as a long-term antiplatelet therapy and at higher doses for the acute treatment of thrombotic events, during cardiovascular procedures, and for pain and fever relief.

IV aspirin is an innovative, stable, and fully soluble intravenous formulation developed to provide a faster-acting alternative to oral aspirin for the initial treatment of acute thrombotic events and during cardiovascular interventions. It is primarily intended for use in suspected myocardial infarction.

[1] A group of conditions caused by sudden, reduced blood flow to the heart, including heart attack (myocardial infarction)

Beyond ACS, IV aspirin can be beneficial in additional cardiovascular indications, including supporting patients following revascularization procedures such as CABG, angioplasty, or carotid endarterectomy, where aspirin therapy is already indicated. Additional indications are currently being evaluated.

About the Pivotal IV Aspirin Study

The pivotal Phase 1 pharmacokinetic, pharmacodynamic and safety study enrolled 40 healthy volunteers to compare a single 325 mg dose of intravenous (IV) aspirin with the same dose of oral aspirin. The primary objective was to demonstrate that IV aspirin is not inferior to oral aspirin in reducing thromboxane B_2 (TXB_2) levels after three hours, a key marker of platelet activity and antiplatelet effect. Secondary endpoints included changes in TXB_2 levels over time, inhibition of platelet aggregation, urinary metabolite levels, and overall safety and tolerability.

No serious adverse events were reported and results showed that IV aspirin achieved equivalent pharmacological response with a faster onset of action compared to oral aspirin. The study was organized by Hyloris' co-development partner Rhoshan Pharmaceuticals, Inc.

About Hyloris Pharmaceuticals

Hyloris is the 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 development portfolio of 26 products, including 23 reformulated and/or 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 2 high barrier generic products approved in the U.S. and 1 high barrier generic product in development. Hyloris continuously evaluates additional product opportunities to drive future growth.

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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