Hyloris Announces Positive Study Results for Dofetilide IV

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

Liège, Belgium – 13 March 2025– 06.30 PM CET — Regulated Information – Inside information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces positive results from a pivotal clinical study evaluating its proprietary Dofetilide IV. The study was designed to compare bioavailability between the intravenous (IV) and oral form of the drug (dofetilide) and to establish optimal dosing strategies, including the initial dose and timing to transition to oral therapy.

This key milestone supports the submission of a New Drug Application (NDA) of Dofetilide IV to the U.S. Food & Drug Administration (FDA) planned in the next months.

Thomas Jacobsen and Stijn van Rompay co-Chief Executive Officers of Hyloris commented: "We are delighted by the successful results of this study. Currently, patients starting dofetilide therapy typically require multiple days of hospitalization to ensure safe dosing and monitoring, primarily due to the need for gradual dose titration and continuous QT interval monitoring[1]. The introduction of Dofetilide IV has the potential to transform this treatment paradigm by enabling a faster and more controlled therapy initiation, potentially reducing hospital stays durations. This study provides essential data to guide dosing recommendations and optimize patient outcomes."

About the study

To support regulatory approval and further validate the benefits of Dofetilide IV, this clinical study assessed the pharmacokinetics and safety of Dofetilide IV. The data generated will be critical for regulatory submission and will help define best practices for Dofetilide IV use in real-world clinical settings.

About Dofetilide IV

Dofetilide is a Class III antiarrhythmic medication indicated for the treatment of atrial fibrillation (AFib) and atrial flutter. It works by selectively blocking potassium channels in the heart, stabilizing electrical

[1] The QT interval is the part of a heart test (ECG) that shows how long it takes for the heart to contract and then reset for the next beat.

activity, and restoring normal rhythm. Currently, dofetilide is only available in oral form and typically requires hospital-based initiation[2] due to the risk of QT prolongation and Torsades de Pointes[3].

Hospital-based initiation involves continuous ECG monitoring, with most patients requiring a 3- to 5-day inpatient stay. The estimated cost of initiation is approximately $3,600[4] per patient per day, based on historical data.

Dofetilide IV is an innovative intravenous (IV) formulation designed to provide controlled administration for patients, such as those who are unable to take oral medication, particularly in acute and emergency settings. Following IV initiation, patients can transition to oral dofetilide for long-term maintenance therapy. Reducing hospital stays could significantly lower healthcare costs, optimize resource use and improve patient convenience.

Dofetilide remains almost exclusively available in the U.S., where it is widely utilised for rhythm management. In 2023, U.S. sales reached 52.2 million capsules, reflecting a 6% increase year-over-year, with a market value of USD 35.8 million (+40%). Newly diagnosed patients typically remain on treatment for 15.6 months of therapy, while other patient groups may continue treatment for 16.7 to 21 months[5] on average. However, some patients are unable to complete the therapy initiation.

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 21 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

[2] A REMS (Risk Evaluation and Mitigation Strategy) program for dofetilide in the U.S. was originally implemented to mitigate the risk of serious ventricular arrhythmias, particularly Torsades de Pointes, which can be life-threatening. Key aspects of the dofetilide REMS Program included that patients were required to be hospitalized for at least 3 days when initiating dofetilide to monitor QT prolongation and kidney function and that only certified healthcare providers and pharmacies were allowed to prescribe and dispense the drug. The REMS requirements for dofetilide were lifted in 2016. However, the boxed warning and strict prescribing guidelines remained in place.

[3] Torsades de Pointes is a life-threatening arrhythmia that can occur when the QT interval (the time it takes for the heart's electrical system to recharge after each heartbeat) becomes prolonged. This condition can lead to fainting, severe dizziness, and sudden cardiac death if not treated promptly.

[4] https://www.ahajournals.org/doi/10.1161/circ.142.suppl_3.16802

[5] Survey commissioned by Hyloris in 2021 on 16 cardiologists and 24 electrophysiologists.

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.

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