Press Release
Non-Regulated Information

Hyloris Receives Exclusive License Option for Innovative Topical Therapy for a Rare Genetic Skin Disorder

Exploratory Trial to be conducted

Liège, Belgium – December 11, 2025 – 17:45 CET – Non-Regulated Information - Hyloris Pharmaceuticals SA ("Hyloris") (Euronext Brussels: HYL), the specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces a research collaboration and exclusive license option agreement with Wake Forest University School of Medicine, a leading U.S. research institution and the academic core of Advocate Health, to advance the development of a new topical therapy utilizing an active substance with a long history of systemic use.

The investigational therapy is intended for patients living with a rare, inherited skin disorder characterized by recurrent flare-ups, chronic inflammation, painful skin lesions, and a significant impact on daily functioning and quality of life. Although the condition is not life-threatening, it is debilitating, often recurring, and currently managed with limited and suboptimal treatment options, leaving many patients without effective long-term relief.

Under the agreement, Wake Forest University School of Medicine will conduct an exploratory clinical trial to evaluate the safety and initial efficacy of the topical therapy. Hyloris has secured an exclusive option to obtain a license and the global commercial rights upon completion of this exploratory trial. A patent application covering its use has been filed and is currently pending in multiple key jurisdictions.

"*This collaboration underscores our commitment to identifying and developing differentiated therapies that can meaningfully improve outcomes for patients with underserved medical needs",* said Stijn Van Rompay, Chief Executive Officer of Hyloris*. "The targeted disorder is both chronic and highly burdensome for patients and remains challenging to manage despite being well understood genetically. We believe that delivering a well-established active substance directly to affected skin areas has the potential to offer a more effective and better-tolerated treatment approach, supporting patients."*

The active substance used in this topical therapy has been widely prescribed in systemic form for many years in an unrelated condition, with an established and well-documented safety profile. Repositioning it for localized delivery aims to maximize therapeutic benefit while minimizing systemic exposure, potentially enabling a streamlined and de-risked development pathway.

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 27 products, including 24 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 and since 2020 listed on Euronext Brussels (EBR: HYL).

For more information, please visit www.hyloris.com and follow-us on LinkedIn.

About Wake Forest University School of Medicine

Wake Forest University School of Medicine, based in Winston-Salem, North Carolina, is the academic core of Advocate Health and a nationally recognized leader in medical education, research, and clinical care. The School educates nearly 1,900 students, residents, and fellows across programs in medicine, physician assistant studies, academic nursing, and biomedical sciences. It is consistently ranked among the top U.S. medical schools for research and innovation, with more than USD 400 million in annual research funding.

The Department of Dermatology at Wake Forest is internationally known for its expertise in complex skin diseases and advanced treatments. It ranks #27 globally for Dermatology research and offers specialized programs in psoriasis, atopic dermatitis, autoimmune skin disease, pediatric dermatology, dermatopathology, and Mohs surgery. Faculty lead multi-center clinical trials and investigator-initiated studies, contributing to breakthroughs in dermatologic care.

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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.

This press release contains information about a product under development and is not intended as a promotional statement.

The product mentioned is subject to regulatory approval and is not currently available for sale. Please consult licensed medical professionals for healthcare decisions.