

Hyloris Announces Partnership with Colonis Pharma for XTRAZA in the UK

Exclusive Licence and Supply Agreement for the UK Signed with Colonis Pharma Ltd. for XTRAZA™ (Tranexamic Acid Oral Rinse)

Liège, Belgium – 3 February 2025 – 7 AM CET – Regulated information – Insider Information

Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that an exclusive licence and distribution agreement has been signed with Colonis Pharma Limited (“Colonis”) for XTRAZA.

XTRAZA™ is a proprietary oral rinse designed to deliver tranexamic acid (an antifibrinolytic agent) to patients on anticoagulant therapies (blood thinners) undergoing dental procedures with bleeding risks, such as tooth extractions. Tranexamic acid has a long history of use in other dosage forms to reduce or prevent postoperative bleeding. XTRAZA represents a novel application in a localised format for optimal coagulation during or after dental interventions.

Under the terms of the agreement Hyloris will receive milestone payments, primarily tied to regulatory achievements, and will exclusively supply XTRAZA in the UK to Colonis.

“Our vision has always been to enhance treatment options for patients and healthcare providers. With XTRAZA, we are aiming to deliver a targeted solution to a distinct clinical need. We are excited to work with Colonis Pharma to make this innovation available in the U.K., contributing to safer, more efficient patient care,” said Stijn Van Rompay, Co-Chief Executive Officer of Hyloris.

Andrew Trouton, Managing Director of Colonis Pharma, commented: “At Colonis we believe that partnerships are key to driving further innovation in healthcare. This partnership with Hyloris Pharmaceuticals will allow the commercialisation of another value-added medicine in the UK, helping to address the unmet medical needs of patients and healthcare professionals”.

In the UK, there are approximately 12,500 registered dental practices¹ and around 43,000 registered dentists². Tooth extraction is a common procedure, often due to tooth decay, with 74% of UK adults having undergone a tooth extraction at some point in their lives with over 80,000 people annually having their wisdom teeth extracted³.

¹ Christie@Co, dental market review 2024

² IBISWorld, General Dental Council

³ <https://www.dentalhealth.org/oral-health-statistics>



About Hyloris

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 19 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 commercialisation 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.

About Colonis Pharma

Colonis Pharmapart of the Clinigen Group, is a UK based company focused on repurposing and developing value-added medicines, addressing unmet needs across several therapeutic areas.

For more information, visit www.colonis.co.uk

About Clinigen

Clinigen is a global, specialist pharmaceutical services company focused on providing ethical access to medicines. Its mission is to accelerate access to medicines for patients in every corner of the globe. The Group supports pharmaceutical and biotech companies across the medical product lifecycle, from clinical through to commercial and operates from sites in North America, Europe, Africa, and the Asia Pacific. Clinigen has more than 1,100 employees across five continents in 15 countries and provides access in more than 130 countries every year.

For more information on Clinigen, please visit <http://www.clinigen.com>.

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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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