Press release
Regulated Information – Inside Information

Hyloris Pharmaceuticals expands its pipeline with a product candidate for a mineral deficiency in the blood (hypophosphatemia)

- Hyloris targets regulatory approval in Europe, with possible further extensions
- About 5% of hospitalized patients is diagnosed with hypophosphatemia, with part of them needing direct treatment during and/or after their hospital stay[1]

Liège, Belgium – January 20th 2023 – 7AM CET – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announced it has in-licensed a product candidate targeting hypophosphatemia. This serious condition causes patients to have a low level of phosphorous in the blood.

While mild hypophosphatemia is common and many patients are asymptomatic, severe hypophosphatemia can be life-threatening and requires medical treatment. The condition can result in different health challenges, including muscle and bone weakness, respiratory or heart failure, seizures or coma.

Deficiency of this vital mineral is always linked to an underlying condition, such as diabetes, anorexia, use of diuretics or alcohol abuse. A more extensive list can be found at the end of this press release under "About Hypophosphatemia".

It is estimated hypophosphatemia affects around 5% of hospitalized patients,[1] and a subpopulation needs direct treatment during and/or after their hospital stay.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"It's a source of pride for us to ensure that drugs administered to patients are accompanied by clear instructions and have demonstrated clinical efficacy and safety. A registered product entails the treatment has been validated by regulators, which ensures fast and equal access and offers peace of mind to physicians and patients."*

"The expected costs for Hyloris stay well below our required average investment of less than EUR 7 million per product candidate. This interesting new opportunity brings us one step closer to a total pipeline of 30 assets, a goal we aim to achieve before 2025."

Treatment protocols for patients deficient in phosphate are well-established and have proven useful in other situations of bone mineral imbalance. Oral administration is the preferred way of treating hypophosphatemia, although in most countries no approved drugs exist. Currently, physicians mostly rely on compounded drugs which have, by definition, not been submitted for regulatory scrutiny regarding safety, efficacy, and quality.

Hyloris will seek advice and approval from regulators by making use of the rich body of clinical data that has emerged from established clinical practice. With a primary on safety of the product, Hyloris intends to conduct a streamlined development program to achieve market access in Europe, targeting regulatory approval in European countries as from 2026.

[1] US numbers from https://www.ncbi.nlm.nih.gov/books/NBK493172/

Global rights of the ongoing development have been licensed-in from Dutch company, QliniQ, who maintains the rights to commercialize the product candidate in its home country, and a selected number of Middle Eastern and developing countries.

The external development cost including the licensing fee is expected to remain below EUR 2 million. Besides agreed upon product development costs that will be incurred, no further payments will be owed to QliniQ.

Albert de Bruin, Managing Director of QliniQ, added: *"Thanks to Hyloris and its demonstrated expertise in bringing new drugs to international markets, our product candidate could help many more patients. We have tremendous confidence in Hyloris' ability to navigate the regulatory path towards improved patient outcomes."*

Separately, Hyloris has divested HY-038 to QliniQ for a price of EUR 1 million. This generic product was considered a non-core asset by Hyloris. This transaction highlights once again an increased focus on value-added repurposed or reformulated product candidates.

About Hypophosphatemia

Hypophosphatemia is a condition where the blood level of phosphorus is low (<2.5mg/dl). This condition can occur due to decrease in oral or intestinal resorption, increased renal excretion or internal redistribution of phosphate.

There is a wide range of underlying conditions leading to hypophosphatemia which could be hereditary (such as X-linked hypophosphatemia, hypophosphatemic rickets, osteomalacia, Cushing syndrome) or acquired (anorexia nervosa, recovery phase of diabetes-related ketoacidosis, alcohol withdrawal, respiratory alkalosis, long term use of diuretic and phosphate binders)[2].

Chronic hypophosphatemia can become life threatening, making direct treatment of the hypophosphatemia desirable in cases where treating the underlying condition does not solve the mineral deficiency.

Many patients are asymptomatic. Symptoms of moderate to severe hypophosphatemia include bone pain, muscle dysfunction, rhabdomyolysis, hemolysis, Leucocyte dysfunction, metabolic encephalopathy, respiratory failure, impaired myocardial performance[3]. Depending on the clinical condition, the standard of treatment is dietary supplement (in mild cases), oral intake (moderate to severe), and intravenous phosphate (Severe)[2].

About QliniQ

QliniQ is a Dutch company which develops and in-licenses drugs and medical supplies in various therapeutic domains and commercializes these in the Netherlands. QliniQ nurtures cooperation and long lasting business relationships with international companies as part of its successful market approach.

About Hyloris Pharmaceuticals SA

[2] Hypophosphatemia - an overview | ScienceDirect Topics

[3] Hypophosphatemia: an evidence-based approach to its clinical consequences and management | Nature Reviews Nephrology

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 portfolio of 16 reformulated and repurposed, with patent applications or patents, value-added medicines that have the potential to offer significant advantages over available alternatives. Outside of its core strategic focus, the Company also has 3 high barrier generic products in development and registration phase. 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 https://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.