Hyloris Announces Partnership with Grand Life Sciences Group for HY-094 in China

- Exclusive License and Distribution Agreement signed with Grand Life Sciences Group for HY-094, an Injectable Iron Product Candidate
- HY-094 Development Moving Forward to Phase III

Liège, Belgium – 27 October 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 announces that an exclusive license and distribution agreement for HY-094, an innovative injectable new chemical entity (NCE) therapy for the treatment of iron deficiency anemia, has been signed with Grand Life Sciences Group. Hyloris and its co-development partner AFT Pharmaceuticals ('AFT') will share the eligible upfront payment, development and sales milestone payments, as well as recurring royalties. In addition, Grand Life Sciences Group will contribute to the global clinical development program.

Iron deficiency remains a common condition that affects around 15% of the world's population. The global intravenous iron drug market is forecasted to grow from around USD 3.2 billion in 2023 to more than USD 7.41 billion by 2033[1]. The Chinese IV iron drugs market is projected to grow from USD 40.0 million in 2024 to USD 151.2 million by 2030, implying a compound annual growth rate (CAGR) of ~24.4 %[2].

While existing IV iron products are effective, they often present tolerability issues, side-effect risks, and frequently require multiple infusions, creating a substantial treatment burden. HY-094 may overcome these limitations. In a randomized clinical trial in 146 patients, HY-094 was compared against both an oral iron therapy and the leading IV iron therapy. The results showed that the efficacy of HY-094 was comparable to existing formulations, that it achieved replenishment of iron deposits and was well tolerated, supporting the prospect of an improved dosing schedule that may require only a single infusion, where existing productss can require multiple. Compared with the leading IV iron product, HY-094 furthermore demonstrated clearly lower administration related complications (2.7% vs. 29.7%); did not, on average, cause a clinically relevant decrease in blood serum phosphate concentrations, which is a key safety result as hypophosphatemia is a safety concern for iron injections, and displayed lower concentrations of free iron in patient urine and blood serum, suggesting a lower toxicity profile. These results indicate that HY-094 may be a safer, more patient-friendly treatment option than current IV iron products.

One or more Phase III clinical trials will be conducted to further evaluate its safety and efficacy. This pivotal study is expected to run until 2028 and will support global regulatory submissions.

"Hyloris is excited that our co-development partner AFT has entered into this agreement with a strong and reputable partner in China. We are confident in the potential of our intravenous iron product and believe this partnership will support its successful introduction and growth in this rapidly expanding market. Awareness of iron deficiency continues to rise, creating significant growth opportunities in intravenous iron sales," said Stijn Van Rompay, Co-CEO of Hyloris. "At the same time, we are very pleased with our robust intellectual property strategy, which we believe provides comprehensive

[1] https://www.biospace.com/intravenous-iron-drugs-market-size-to-worth-around-us-7-41-billion-by-2033
[2] https://www.grandviewresearch.com/horizon/outlook/intravenous-iron-drugs-market/china?utm_source=chatgpt.com

protection for our product. Combined with the well-known challenges in developing generic versions of IV iron products, this reinforces our confidence in the product's long-term sustainable value."

This transaction was facilitated with the support of Ms Hong Xie from Pharma China Consulting, who provided advisory services.

About Iron Deficiency

Iron deficiency, the most common nutritional disorder globally, occurs when the body lacks adequate iron to produce hemoglobin, the protein in red blood cells that carries oxygen. While oral and intravenous iron products are available, many patients struggle with side effects, adherence issues, or accessibility challenges, underscoring the need for improved treatment options.

Iron deficiency affects around 1.3 billion people[3]. It is especially common among young children, pregnant women, and those with chronic conditions like chronic kidney disease and inflammatory bowel disease. This deficiency can cause anemia and can impact immune function, and overall physical health, leading to symptoms like fatigue, lowered immunity, and diminished cognitive performance. Although iron deficiency alone impacts roughly 15% of the global population, only a fraction of these individuals receive intravenous (IV) iron products, often due to limited access and side effects associated with available treatments. Although iron-rich diets and oral supplementation can increase iron levels, they are often insufficient due to limited bioavailability, the long duration of therapy required, and poor adherence caused by gastrointestinal side effects. As a result, intravenous (IV) iron therapy remains a critical approach for treating anemia associated with various conditions across nephrology, oncology, cardiology, gynaecology, and gastroenterology.

The iron deficiency treatment market is projected to grow steadily, driven by rising rates of chronic disease, dietary insufficiencies, and aging populations. Current treatment options include various IV formulations, such as Ferric Carboxymaltose, Iron Dextran, and Iron Sucrose.

About Hyloris Pharmaceuticals SA

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 existing regulatory pathways, such as the FDA's 505(b)2 pathway in the U.S or similar regulatory frameworks in other region which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This type of regulatory 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 has built a broad development portfolio of 26 products, including 23 reformulated and/or repurposed value-added medicines. 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

[3] Prevalence, years lived with disability, and trends in anaemia burden by severity and cause, 1990–2021: findings from the Global Burden of Disease Study 2021 - PMC

Company has 2 high barrier generic products approved in the U.S. and 1 high barrier generic product in development.

Hyloris is based in Liège, Belgium and listed on Euronext Brussels (XBRU:HYL). For more information, visit www.hyloris.com and follow-us on LinkedIn.

About Grand Life Sciences Group Co., Ltd.

Grand Life Sciences Group Co., Ltd. ("Grand Life Sciences") is a leading Chinese biopharmaceutical company focused on the development and manufacturing of plasma-derived therapies, probiotics, vaccines, medical nutrition, and peri-operative care solutions. Headquartered in Chengdu, China, Grand Life Sciences combines deep scientific expertise with state-of-the-art manufacturing and quality systems to deliver high-value biologics across multiple therapeutic areas.

For more information, visit www.cgeinc.com/en/index.html

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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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