Hyloris Announces a New Product Candidate Targeting Iron Deficiency

- Late-Stage Development for Novel Injectable Iron Therapy in Partnership with AFT Pharmaceuticals (AFT) Targeting a USD 7.4 Billion Global Market[1]

Liège, Belgium – 31 March 2025, 07:00 AM CET – Regulated information – Inside information -Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs by enhancing and repurposing existing medications, today announces it has entered into a late-stage research and development program in collaboration with AFT Pharmaceuticals (AFT) to introduce an innovative injectable iron deficiency therapy (HY-094) to the global market. As part of this program, Hyloris and AFT have secured an exclusive global IP license covering human use.

Iron deficiency remains a common condition that affects 15% of the world 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[2].

Existing iron treatments often present significant challenges and frequently require multiple infusions. The new innovative product candidate, which has completed Phase 2b trials, aims to address limitations of current options by offering a more patient–friendly treatment.

Under the terms of the agreement, Hyloris and AFT will co-develop the candidate for registration and global commercialization. Hyloris will oversee product formulation, manufacturing, and the commercialisation efforts in Europe. AFT will manage the clinical trials, execution and the commercialisation outside Europe. Parties are jointly responsible for commercialization in the United States. A Phase 3 clinical trial(s) involving approximately 1,000 or more patients will be conducted for investigation of efficacy and safety. Development costs, as well as all net margin from sales and licensing, will be distributed equally between AFT and Hyloris, after a tiered profit participation for the licensor.

“Hyloris is committed to expanding options for patients managing chronic conditions, including iron deficiency,” said Stijn Van Rompay, Co-CEO of Hyloris. “Our new iron deficiency treatment has shown great potential in Phase 2, and we’re excited to work with AFT on an additional product. This product offers a significant opportunity to support patients worldwide by making iron infusion therapy simpler and more accessible. With Phase 3 trials set to commence in the near future, we anticipate bringing this innovative therapy to market in line with Hyloris' standard product selection criteria and within our usual product development budget of EUR 7 million.”

The company anticipates that the product will enhance therapeutic options available to healthcare providers and will be backed by a robust IP strategy.

[1] https://www.biospace.com/intravenous-iron-drugs-market-size-to-worth-around-us-7-41-billion-by-2033
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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 therapies 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 not only causes anemia but also impacts immune function, and overall physical health, leading to symptoms like fatigue, lowered immunity, and diminished cognitive performance. Although iron deficiency anemia alone impacts roughly 15% of the global population, only a fraction of these individuals receives intravenous (IV) iron therapies, often due to limited access and side effects associated with available treatments. Although iron-rich diets and oral supplementation can raise iron levels, they are often insufficient due to limited bioavailability, making IV iron therapy a critical approach to treating anemia linked to numerous 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, patented portfolio of 22 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Two products are currently in early phases of commercialization with partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. Outside its core strategic focus, the Company also 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.

[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

About AFT Pharmaceuticals Ltd

AFT is a listed (NZE: AFT) and growing multinational pharmaceutical company that develops, markets, and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories. Its business model focuses on developing and in-licensing patented, branded, and generic products for commercialization. AFT Pharmaceuticals has direct operations in Australia, New Zealand, Singapore, Hong Kong, South Africa, Canada, and the United Kingdom and has out-licensed products to licensees and distributors in over 120 countries worldwide.

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Hyloris means “high yield, lower risk”, which relates to the 505(b)(2) regulatory pathway for product approval on which the Issuer 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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