Hyloris Broadens Pipeline with new Product Candidate for Vulvar Lichen Sclerosus (VLS)

- Equal Partnership with AFT Pharmaceuticals for Development of a Drug Releasing Mucoadhesive Film for VLS (HY-091)
- Limited Availability of Approved Treatment Options in VLS

Liège, Belgium – 18 January 2024, 07:00 PM CET – Regulated information – Inside information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that it has entered into a partnership with AFT Pharmaceuticals (AFT) to develop a novel mucoadhesive film for the treatment of Vulvar Lichen Sclerosus. HY-091 targets to have an extended duration release of a known molecular entity and to offer a convenient application method, ensuring simplicity and improving compliance.

Under the terms of the agreement, Hyloris and AFT will co-develop HY-091 for the purpose of registration and worldwide commercialization. Hyloris is responsible for ensuring the product formulation, manufacturing activities and the coordination of the commercialisation in Europe. AFT is responsible for managing the clinical trials, overseeing all aspects to ensure effective planning, execution and monitoring throughout the trial lifecycle, and the coordination of the commercialisation outside of Europe. Parties are jointly responsible for commercialization in the United States.

Stijn Van Rompay, Chief Executive Officer of Hyloris, added: "*I am pleased to announce an additional co-development with AFT. This partnership and the recently announced collaboration on HY-090 for Burning Mouth Syndrome are a testament to our shared commitment to making a meaningful impact on the healthcare system. By combining our resources and expertise, we are poised to pioneer innovative solutions for patients suffering from VLS.*"

About Vulvar Lichen Sclerosus [1][2][3]

Vulvar Lichen Sclerosus (VLS) is a chronic, distressing, inflammatory disease with an enormous impact on quality of life. HY-091 is designed as a user-friendly mucoadhesive film product with a convenient application method that ensures simplicity and compliance, offering targeted relief for patients experiencing the discomfort, itching, and pain associated with Vulvar Lichen Sclerosus by reducing inflammation and scarring in the affected area of skin and helping in restoring the skin structure. There is no curative treatment for VLS, which usually occurs in postmenopausal women, although children and premenopausal women may be affected. Advanced condition severely affects the quality of life and is associated with increases risk of vulvar squamous cell carcinoma. It is a massively under diagnosed condition, which affects 0.1% to 3% of the general population.

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

[1] https://www.uptodate.com/contents/vulvar-lichen-sclerosus-beyond-the-basics

[2] https://www.jogc.com/article/S1701-2163(21)00890-2/fulltext

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5496281/

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 18 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.

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 is to develop and in-license patented, branded and generic products which are promoted through its dedicated sales teams in Australia, New Zealand and selected Southeast Asian markets, and to out-license its products to local licensees and distributors in over 125 countries around the world.

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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 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.