Hyloris Broadens Pipeline with new Product Candidate in Burning Mouth Syndrome

- Equal Partnership with AFT Pharmaceuticals for Development of a Novel Locally-Acting Product Candidate in Burning Mouth Syndrome (HY-090)
- Strengthening Strategic Partnership with AFT Pharmaceuticals Following the Success of the Maxigesic® IV Collaboration

Liège, Belgium – 21 December 2023, 06:30PM 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 co-develop HY-090, a novel locally-acting product candidate for the treatment of Burning Mouth Syndrome (BMS).

Under the terms of this equal partnership agreement, targeting co-development and worldwide commercialisation, 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: *"This collaboration brings together the strengths of Hyloris and AFT, combining strong internal R&D capabilities and solid expertise in clinical trial management. Together, we combine our expertise to drive innovation and aim to deliver unparalleled value to patients. I look forward to the successful outcome and positive impact that will result from this strategic collaboration, as it aligns with the collective mission to provide much-needed relief for individuals living with Burning Mouth Syndrome."*

About Burning Mouth Syndrome [1] [2]
Burning mouth syndrome (BMS) is characterized by burning pain in a normal-appearing oral mucosa lasting at least four to six months. The condition is idiopathic, and the underlying pathophysiology is not well understood. Patients with burning mouth syndrome commonly experience changes in gustatory function. The reported prevalence ranges from 0.7% to 5% of individuals in the US[3] and occurs more frequently in women than men, with a female to male ratio of 7:1. Prevalence increases with age in both men and women, with the highest prevalence reported in postmenopausal women aged 60–69 years.

About AFT Pharmaceuticals
AFT (ASX: AFP, NZX: AFT) is a specialty pharmaceutical company that operates primarily in Australasia but has product distribution agreements across the globe. The company's product portfolio includes prescription and over-the-counter (OTC) drugs to treat a range of conditions.

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. Hyloris has built a broad, patented portfolio of 17 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over

[1] https://www.ncbi.nlm.nih.gov/books/NBK519529/
[2] https://www.sciencedirect.com/science/article/pii/S2772559622000049
[3] based on combination of different sources: population-based study, clinical based study and key opinion leaders' estimation

available alternatives. Outside of its core strategic focus, the Company also has 1 approved high barrier generic product launched in the U.S. and 2 high barrier generic product candidates in development.
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 www.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 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.