Orphan Drug Designation Granted to PTX-252 by U.S. FDA for the Treatment of Acute Myeloid Leukaemia (AML)

PTX-252 (previously referenced as a Plecoid™Agent) is a novel molecular entity developed in collaboration with Pleco Therapeutics

Liège, Belgium – 16 January 2024, 07:30PM CET – Non-Regulated information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to PTX-252 for the treatment of Acute Myeloid Leukaemia (AML). This product candidate, developed in collaboration with Pleco Therapeutics BV incorporates a novel molecular entity that is a derivative of a known established molecule and is designed to enhance the responsiveness of cancer cells to chemotherapy.

Obtaining an Orphan Drug Designation provides incentives and benefits to encourage the development of treatments for rare diseases. These include financial incentives, market exclusivity and support in navigating regulatory processes.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"Securing orphan drug designation for a product candidate incorporating a novel molecular entity, not yet approved by any regulatory agency, underscores our unwavering commitment to advancing the frontiers of scientific discovery within the repurposing space."*

Ivo Timmermans, Chief Executive Officer of Pleco Therapeutics, added: "*This milestone underscores our commitment to innovative therapies for rare diseases and it brings hope to AML patients who have limited treatment options. Our team is dedicated to advancing this therapy through clinical development as swiftly as possible."*

About Acute Myeloid Leukaemia (AML)[1]
AML is a type of heterogenous haematological malignancy that originates from immature white blood cells (blasts) in the bone marrow, which may be derived from either a hematopoietic stem cell or a lineage-specific progenitor cell. AML generally spreads quickly to the bloodstream and can then spread to other parts of the body including lymph nodes, spleen, central nervous system, and testicles. AML is primarily a disease of the adulthood; the median age of newly diagnosed AML patients is around 67 years. Additionally, AML is more common in males. AML can arise de novo or secondarily either due to the progression of other diseases or due to treatment with cytotoxic agents. GlobalData estimates that in 2022, there were 148,351 diagnosed prevalent cases of AML in major markets and expects that the number will increase to 185,323 by 2032.

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 available alternatives. 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. 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

1 Datamonitor Healthcare April 2021; Leukemia & Lymphoma Society, 2019; WHO classification of AML, 2016

development. 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.

About Pleco Therapeutics
Pleco Therapeutics is a clinical stage specialty biopharmaceutical company that aims to improve the survival rate of cancer patients through its novel Plecoid™ therapies that increase the effectiveness of current cancer treatments. As private company, Pleco is headquartered in Nijmegen, the Netherlands, with a U.S. subsidiary, Pleco Therapeutics USA Inc, based in Newark, New York.

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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.