Hyloris Broadens Pipeline with Novel Patented Combination Product Candidate in Acute Myeloid Leukaemia and Small Cell Lung Cancer

Strategic partnership with Pleco Therapeutics for a novel combination product of chelating agents in AML and SCLC

Hyloris to commit €1 million, convertible into equity, plus pre-defined R&D funding through to regulatory submission

Liège, Belgium – 10 November 2021, 7:00am CET – 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 strategic partnership with Pleco Therapeutics to develop a Plecoid™ Agent, a novel combination product of chelating agents for the treatment of Acute Myeloid Leukaemia (AML) and Small Cell Lung Cancer (SCLC).

The Plecoid fixed-dose combination product is a patented, innovative, clinical-stage product candidate that combines chelating agents with different characteristics and aims to detoxify the cancer promoting cellular micro-environment and improve the effectiveness of chemotherapy in patients. Previous studies demonstrate that elevated levels of toxic metals are associated with inferior survival in patients with AML. Exploratory clinical studies are currently ongoing in AML patients to evaluate the metal rebalancing effect of chelating agents administered concomitantly with chemotherapy.

Ivo Timmermans, Chief Executive Officer of Pleco Therapeutics B.V., commented: "*We have developed Plecoid Agents based on breakthrough research performed at the MD Anderson Cancer Center[1], which evidenced that many AML patients have significantly elevated levels of toxic metals in their bone marrow and blood, resulting in poor overall survival.[2] We are very encouraged by the interim results from an exploratory clinical study, which demonstrated that the administration of chelating agents with standard of care chemotherapy resulted in complete remission in 85% of high-risk AML patients in this study. We are very excited to partner with Hyloris and look forward to our discussions with the FDA and mapping-out the clinical development strategy that is required for approval in AML.*"

Stijn Van Rompay, Chief Executive Officer of Hyloris, added: "*This partnership is a great endorsement of our focused strategy and demonstrates that we are delivering on our promise to enlarge the R&D pipeline with 4 candidate products this year. We are on track to expand the portfolio with another candidate medicine before year-end and remain fully funded to advance the current product portfolio, in line with our business plan. We will also explore various financing options to accelerate our ambitious growth plans and support our shift towards higher value repurposed products to address unmet medical needs and create shareholder value.*"

Jean-Luc Vandebroek, Chief Financial Officer of Hyloris, concluded: *"By committing to an investment of €1 million in Pleco Therapeutics, we gain global exclusive co-development rights and future joint commercialisation to this breakthrough Plecoid chelating agent, while limiting upfront financial exposure and risk until we have had feedback from the FDA and embark on the development plan. Together with the medical team at Pleco, we are now looking forward to the consultations with the regulatory bodies in the U.S., which are planned over the next coming months."*

[1] The University of Texas MD Anderson Cancer Center is devoted exclusively to cancer patient care, research, education and prevention and ranks No. 1 in cancer care in the U.S. News & World Report's 2020-21 "Best Hospitals" survey
[2] Ohanian et al, Journal of Hematology, January 2020

Under the terms of the agreement, Hyloris will provide €1 million (automatically convertible into Pleco Therapeutics equity under certain conditions) in several tranches over time and has obtained global exclusive co-development rights and future joint commercialisation to the Pleco technology in AML and SCLC. Subject to feedback from the FDA on the feasibility of the clinical development requirements, Hyloris may commit to fund (not convertible into equity) up to an additional €7.7 million in pre-defined R&D activities through to submission for approval in AML, plus initial exploratory development work in SCLC. Pleco will fund all activities that are outside the scope of the maximum €7.7 million funding commitment from Hyloris. Hyloris will be eligible to receive up to 65% of the gross product margin generated worldwide in AML and SCLC.

About Acute Myeloid Leukaemia (AML)[3]
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 an orphan disease and is the most common type of acute leukaemia in adults and 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. Datamonitor Healthcare estimates that in 2018, there were 158,400 incident cases of AML worldwide and expects that the number will increase to 169,000 by 2027.

About Pleco Therapeutics B.V.
Pleco Therapeutics is a specialty biopharmaceutical company which aims to extend the life span and enhance the quality of life of patients through its novel Plecoid™ therapies that are designed to dramatically increase the effectiveness of current cancer treatments. These novel Plecoid™ therapies have the potential to positively change the balance of protein expression within the cancer microenvironment, removing the burden of toxic metals within the cell, thereby improving the effectiveness of existing chemotherapy. Pleco is based in Nijmegen, the Netherlands.

About Hyloris Pharmaceuticals SA
Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimising 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 14 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Outside of its core strategic focus, the Company also has 3 high barrier generic products in development and registration phase. Two products are currently in initial phases of commercialisation 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.

For more information, please contact:
Hyloris Pharmaceuticals, Investor Relations and Media
investorrelations@hyloris.com

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

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.