Press Release
Regulated Information – Inside information

Hyloris Partners with Kuvatris Therapeutics to Advance Suramin IV Development for Sleeping Sickness, Targeting a Priority Review Voucher

- Strategic Partnership Includes USD 2 Million R&D Funding and USD 1.6 Million Equity Investment by Hyloris
- Program Targets FDA Approval of Suramin IV for Human African Trypanosomiasis (HAT) by 2027, and, Upon Approval, Qualifies for a Tropical Disease Priority Review Voucher (PRV)
- Recent PRV Sales Have Closed at Values Close to USD 150 Million[1]

Liège, Belgium – June 23, 2025 – 07:00 CET – Regulated Information – Inside information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medicines, today announced the signing of an R&D funding agreement to support the development of Intravenous (IV) Suramin, an investigational treatment for human African trypanosomiasis (HAT), also known as African sleeping sickness. The program is being developed by Kuvatris Therapeutics (Kuvatris), a privately held, U.S.-based company.

Hyloris will provide up to USD 2 million in milestone-based funding over the next 12-18 months, with the goal of advancing the program - currently in phase 3 of development - toward U.S. Food and Drug Administration (FDA) approval by 2027. If approved, Suramin IV will qualify for a PRV, a transferable regulatory incentive that has historically commanded significant commercial value. As part of this strategic collaboration, Hyloris will be entitled to just over 50% of the net proceeds from the sale of the PRV.

In addition, upon closing, Hyloris will make an equity investment of USD 1.6 million, thereby acquiring just under 20% ownership in Kuvatris. This investment further aligns Hyloris' long-term interests with the success of the Suramin IV program and strengthens its strategic position.

HAT is a parasitic disease transmitted by infected tsetse flies, primarily affecting populations in sub-Saharan Africa. Left untreated, the disease can cause severe neurological damage and death. While Suramin IV is an established antiparasitic treatment in several African countries, it has not yet been approved in the United States.

Kuvatris is also developing Suramin as a potential treatment for the symptoms of autism spectrum disorder (ASD). If the FDA approves Suramin for HAT and a PRV is awarded and sold, Kuvatris plans to use part of the proceeds to fund further clinical trials in ASD. If Hyloris then decides to contribute co-funding of 20 percent - up to USD 3 million - to the ASD clinical trials, it will receive 20 percent of any future returns from that indication. Aside from this potential contribution, Hyloris does not expect to make further investments in Kuvatris.

Hyloris, commented: "This strategic partnership and equity investment in Kuvatris underscores our commitment to addressing neglected diseases and unlocking the value of regulatory incentives. By supporting Kuvatris' development of Suramin IV for human African trypanosomiasis (HAT), we aim to

[1] Priority Review Vouchers: By the Numbers - BioSpace

obtain a Priority Review Voucher (PRV) - a highly valuable and transferable regulatory asset. Hyloris is entitled to receive slightly over half of the net sales proceeds of any PRV awarded. Recent PRV transactions (since mid-2024) have been in the range of USD 150 million, with specific deals closing at or above that level. The recent rise in PRV sale prices has been driven primarily by the declining availability of Rare Pediatric Disease PRVs, as that program approaches its legislative sunset. While Tropical Disease PRVs remain accessible under current legislation, the overall supply of PRVs is limited, and these vouchers continue to be highly valued by companies seeking expedited FDA review."

Kuvatris added: "We are very pleased to partner with Hyloris, whose proven track record with the FDA, combined with deep regulatory and clinical expertise, makes them an ideal strategic counterpart in the advancement of Suramin IV toward U.S. approval. This collaboration represents a significant milestone in our mission to deliver impactful therapies for underserved patient populations."

About Human African Trypanosomiasis (HAT)
Human African trypanosomiasis, commonly referred to as African sleeping sickness, is a parasitic disease caused by protozoa of the species *Trypanosoma brucei* and transmitted to humans through the bite of infected tsetse flies, which are found in 36 countries in sub-Saharan Africa. There are two forms of the disease: one caused by *Trypanosoma brucei gambiense*, which leads to a chronic infection primarily in West and Central Africa, and another caused by *Trypanosoma brucei rhodesiense*, which leads to an acute form of the disease mainly in East and Southern Africa. Suramin IV is being developed specifically for the treatment of the *T. b. rhodesiense* form which tends to progress more rapidly. In recent years fewer than 1,000 new cases have been reported annually[2]. Cases of HAT in the U.S. are extremely rare, with cases typically arising among travellers, expatriates, or populations having visited or lived in endemic regions of Africa.

Suramin has been the standard of care for the treatment of the early stage of the East African form of HAT (Trypanosoma brucei rhodesiense) for more than 100 years and is listed on the Centers for Disease Control (CDC) formulary. It is currently in short supply worldwide and supplied by the World Health Organization (WHO) as one of the world's essential medicines[3], but it has never been approved by the FDA for use in the U.S. for any indication.

The U.S. Food and Drug Administration (FDA) has already granted an orphan drug designation to IV Suramin for the treatment of HAT.

About Tropical Disease Priority Review Voucher
A Tropical Disease Priority Review Voucher (PRV) is awarded by the U.S. FDA to companies that develop and gain approval for treatments targeting (often) neglected tropical diseases[4]. The voucher grants priority review for any drug submitted to the FDA, shortening the average review time to as little as 6

[2] World Health Organization. *Human African Trypanosomiasis (sleeping sickness)*. Fact Sheet. Accessed April 2025. Available at: https://www.who.int/news-room/fact-sheets/detail/trypanosomiasis-human-african-(sleeping-sickness)
[3]World Health Organization. *WHO Model List of Essential Medicines - 23rd list, 2023* Available at: https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02
[4] GAO-20-251, DRUG DEVELOPMENT: FDA's Priority Review Voucher Programs

months. PRVs are transferable and can be sold[5]. This creates a strong financial incentive to develop treatments for diseases with limited commercial potential.

About Autism Spectrum Disorder

Autism spectrum disorder (ASD) is a neurodevelopmental condition characterized by challenges with social interaction, communication, and restricted or repetitive behaviors. It affects individuals worldwide, with a global prevalence estimated at approximately 1 in 100 children[6], with the U.S. recently reporting rates as high as 1 in 31 children.[7] There remains a need for new therapeutic approaches that address the core symptoms of the disorder.

Kuvatris conducted a Phase 2 clinical trial of Suramin IV for ASD. This randomized, double-blind, placebo-controlled study enrolled 52 boys aged 4–15 years with moderate to severe ASD. The trial was conducted across six sites in South Africa, where suramin is a registered medicine. The study aimed to evaluate the safety and efficacy of intravenous suramin infusions administered at doses of 10 mg/kg and 20 mg/kg, compared to placebo. Infusions were given at baseline, week 4, and week 8, with a 6-week follow-up period. The primary endpoint was the change from baseline in the Aberrant Behavior Checklist (ABC) Core score, which assesses core symptoms of ASD. Secondary endpoints included the Clinical Global Impressions-Improvement (CGI-I) scale and other behavioral assessments. The trial provided supportive safety data and preliminary signals of clinical efficacy, especially at the 10 mg/kg dose, warranting further investigation. The study showed positive signals in improving language, social interaction, and behavior in children with ASD.

Hyloris has not committed to participating in the development of Suramin for ASD, but holds the option to do so. Any future involvement by Hyloris would depend on successfully obtaining the PRV and would be funded through proceeds from its eventual sale.

About Hyloris Pharmaceuticals

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 payers.

The Company's development strategy primarily focuses on leveraging established regulatory pathways, such as the FDA's 505(b)2 pathway in the U.S. or equivalent regulatory frameworks in other regions which are specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This approach can reduce the clinical burden required for market entry, and significantly shorten the development timelines, leading to reduced costs and risks.

[5] Any potential sale of the Priority Review Voucher (PRV) is subject to the successful regulatory approval of the underlying product, uncertainties related to timing, pricing, and prevailing market conditions, and the continued existence of the PRV program which has been permanently authorized under U.S. law since 2007.

[6] World Health Organization. *Autism spectrum disorders*. Fact Sheet. Accessed April 2025. Available at: https://www.who.int/news-room/fact-sheets/detail/autism-spectrum-disorders

[7] CDC Morbidity and mortality Weekly Report Prevalence and Early Identification of Autism Spectrum Disorder April 17, 2025 Available at: Prevalence and Early Identification of Autism Spectrum Disorder Among Children Aged 4 and 8 Years — Autism and Developmental Disabilities Monitoring Network, 16 Sites, United States, 2022 | MMWR

Hyloris has built a broad, patented portfolio of 23 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over existing alternatives. Two products are currently in early phases of commercialization in collaboration with commercial partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. In addition to its core strategic focus, the Company has 2 approved high barrier generic product approved in the U.S. and 1 high barrier generic product in development.

Hyloris is based in Liège, Belgium. For more information, visit www.hyloris.com and follow-us on LinkedIn.

About Kuvatris Therapeutics

Kuvatris Therapeutics is a late-stage biopharmaceutical company developing anti-purinergic therapies to address critical unmet medical needs in both rare diseases and neurodevelopmental disorders. The company's lead program targets two distinct but strategically linked markets.

Kuvatris is advancing Suramin IV toward FDA approval for human African trypanosomiasis (HAT), addressing a critical global health need where current supply shortages have created treatment access challenges. Suramin has served as the standard of care for early-stage East African sleeping sickness for over a century, but has never been approved in the United States, leaving American physicians without access when rare cases occur.

Building on extensive experience in HAT treatment, Kuvatris is also developing Suramin for autism spectrum disorder (ASD), where the company has completed a Phase 2 randomized, double-blind, placebo-controlled trial demonstrating preliminary signals of efficacy in improving core symptoms including language, social interaction, and behavior in children with ASD. This represents a potentially first-in-class approach to treating the underlying symptoms of autism rather than managing associated behaviors alone. The company plans to leverage HAT approval to unlock value from the sale of a potential Priority Review Voucher to fund advancement of Suramin's use in autism and receive exclusive commercial access to the U.S. market.

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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 Company 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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