Press Release
Regulated Information -Inside Information

Hyloris Licenses European and Turkish Rights to Next-Generation Wilson's Disease Candidate from ArborMed

- Hyloris Obtains Exclusive License Rights in Europe and Turkey from ArborMed for its Investigational Wilson's Disease Therapy, Including an Upfront Payment of USD 2 million
- Wilson's Disease is a Rare, Inherited Metabolic Disorder that Causes Toxic Copper Accumulation in the Body
- The Agreement Includes a Conditional Option Allowing ArborMed to Reacquire these Rights under Predefined Terms and Conditions

Liège, Belgium – 30 December 2025 – 06:00 PM CET – Regulated Information – Inside Information- Hyloris Pharmaceuticals SA ("Hyloris") (Euronext Brussels: HYL), the specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announced that it has entered into a license agreement granting exclusive rights in Europe and Turkey with South Korea–based ArborMed for a novel injectable product candidate for Wilson's disease.

Next-generation product candidate for Wilson Disease Therapy

Wilson's disease is a rare inherited metabolic disorder in which copper accumulates in the body to toxic levels. In early stage it primarily affects the liver and can cause progressive, severe damage to the organ. Late-stage disease can also affect other organs, most notably the brain, leading to serious neurological complications, including cognitive impairment and Parkinson's-like symptoms. If left untreated, Wilson's disease can progress to liver failure requiring transplantation and can be fatal.

ArborMed's investigational product candidate is a next-generation copper chelator[1] designed to address key limitations of existing therapies. ArborMed's product candidate stands out for its exceptional affinity and selectivity for copper ions. This may provide a therapeutic advantage through more effective binding and removal of excess copper. Unlike current treatments that often require daily administration, ArborMed's product candidate has shown the ability to halt and even reverse early disease in non-clinical disease models. This profile supports the potential for intermittent dosing, potentially spaced weeks apart, offering a more convenient approach for patients.

The product candidate has undergone extensive non-clinical evaluation, demonstrating strong copper-binding characteristics and supporting safety data in established disease models. ArborMed plans to initiate its first-in-human clinical trial in 2026 in healthy volunteers and start evaluating the candidate in Wilson's disease patients by 2027. This approach enables a streamlined clinical program to generate data on efficacy and safety and to demonstrate copper-binding performance in the target population.

[1] A chelator is a compound that binds tightly to metal ions

Building value through strategic, flexible partnering

Under the terms of the agreement, Hyloris will pay an upfront license fee of USD 2 million to support ArborMed's ongoing development program. In return, Hyloris obtains an exclusive license to commercialise the product candidate in all European countries and Turkey, with the right to sub-license. Hyloris will not be required to make any additional upfront payments under the agreement. Depending on the commercialisation route selected by Hyloris, ArborMed will be entitled, either to a substantial share of future profits generated by Hyloris (in the event of a sub-license), or to a combination of royalties and sales milestone payments if Hyloris commercialises the product candidate directly.

ArborMed also retains a contractual option to reacquire the rights held by Hyloris prior to the initiation of Phase 3 clinical trials, provided that ArborMed secures a broader licensing or partnership transaction covering Europe. If this option is exercised under the agreed terms, Hyloris will receive reimbursement of its upfront license fee and will remain entitled to ongoing payments, structured either as a significant minority share of profits generated in Europe and Turkey or as a low double-digit percentage of global profits, reflecting the value contributed by Hyloris, with ArborMed having the ability to recoup certain agreed development and commercialisation expenses, provided that a minimum level of profit participation remains payable to Hyloris at all times, including during any recoupment period.

Stijn Van Rompay, CEO of Hyloris, said: *"Wilson's disease still presents major therapeutic challenges, and a more selective metal chelator could make a real difference for patients. While Hyloris is well-known for smart reformulations and repurposing strategies, we are prepared to support selected new chemical entity programs where the scientific rationale is compelling, the differentiation is clear, the development pathway is well defined and our overall exposure is de-risked. This product candidate meets all those criteria and we are pleased to support this promising therapy. Going forward we will consider out-licensing the rights to a strong commercial partner or, alternatively, ArborMed exercising its option to repurchase the rights held by Hyloris. If approved, we believe it could support an in-market sales price in the tens of thousands of euro per patient per year. With 28 products already announced, and additional assets at an early stage of internal development, Hyloris' development pipeline today comprises 30 or more diversified products and candidates."*

Kyojin Park, CEO ArborMed, added: "*Wilson's disease represents a significant unmet medical need and a commercially attractive rare-disease opportunity, with patients often requiring lifelong treatment and facing substantial clinical and economic burden. We believe this candidate is uniquely positioned, with the potential to meaningfully improve outcomes for patients. Partnering with Hyloris strengthens the program and provides strategic co-building and flexibility as we advance toward later-stage development and broader partnering opportunities*."

About Wilson's Disease

Wilson's disease is a rare genetic disorder caused by mutations in the ATP7B gene, leading to impaired copper excretion and progressive accumulation of copper in the liver, brain, and other organs.

The disease is typically progressive: silent copper build-up in early life gradually leads to liver disease, neurological impairment, and psychiatric symptoms. If untreated or insufficiently treated, Wilson's disease can result in irreversible organ damage and can be life-threatening. Long-term management requires sustained control of copper levels, including chelation and/or other copper-reducing approaches.

Prevalence estimates vary by population and methodology but are commonly cited in the range of 1 to 9 in 100,000[2]. In the European Union, the disease affects up to 6 per 100,000 people (around 31,000 individuals)[3].

About Hyloris Pharmaceuticals

Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimizing existing medications through reformulation and repurposing to address important healthcare needs and deliver meaningful 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 and regulatory burden required for market entry, and significantly shorten development timelines, leading to reduced costs and risks.

Hyloris has announced a broad development portfolio of 28 products, including 25 value-added medicines of which two are currently in early stages 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 two high-barrier generic products approved in the U.S. and one additional high-barrier generic product in development. Beyond its announced portfolio, Hyloris has initiated several additional internal early-stage development activities, bringing the total pipeline to more than 30 products and product candidates, and continues to evaluate further product opportunities to support future growth.

Hyloris is based in Liège, Belgium and listed on Euronext Brussels (EBR: HYL). For more information, visit www.hyloris.com and follow-us on LinkedIn.

About ArborMed

ArborMed is a South Korea-based biopharmaceutical company focused on developing innovative therapies for rare and intractable diseases, pursuing rapid development, approval, and commercialization based on scientific evidence and clinical execution capabilities. In addition to the Wilson's disease product candidate licensed to Hyloris (ARBM-101), the company is developing a pipeline of therapeutic candidates targeting congenital hearing loss, acute respiratory distress syndrome (ARDS), and other indications. For more information, visit www.arbormed.com

[2] https://www.orpha.net/en/disease/detail/905
[3] https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu-3-15-1471

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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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