Hyloris Broadens Pipeline with RedHill's Ondansetron Extended-Release

- Exclusive Licensing Agreement Signed with RedHill Biopharma for a Novel, Bimodal, Extended Release ('ER') Formulation of the Antiemetic Drug Ondansetron
- Aiming to Improve Therapeutic Outcomes, Convenience and Compliance

Liège, Belgium – 25 February 2025, 07:00 AM 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 announced that it has entered into an exclusive licensing, development and commercialisation agreement with RedHill Biopharma (Nasdaq: RDHL) for a once-daily, proprietary, bimodal extended-release oral tablet formulation of ondansetron[1]. The agreement grants Hyloris exclusive global rights outside of North America.

This extended-release formulation of the 5-HT3 antagonist ondansetron is designed to provide prolonged relief from nausea and vomiting associated with chemotherapy, radiotherapy (also known as CINV/RINV), and post-operative recovery. It aims to enhance patient convenience and facilitate better management of symptoms during intensive treatments. The global CINV/RINV 5-HT3 antagonist market was estimated at USD 1,5 billion in 2024 and is growing at a compound annual growth rate (CAGR) of approximately 5,3%[2].

"Ondansetron ER will be a valuable addition to supportive care in oncology and post-surgical settings, where sustained relief from nausea is essential," said Thomas Jacobsen, Co-Chief Executive Officer of Hyloris. "We are committed to delivering innovative solutions that enhance patient comfort and streamline therapy, especially in areas where reducing treatment burden can make a meaningful impact. We look forward to collaborating with RedHill to bring this product to patients."

Dror Ben-Asher, CEO of RedHill Biopharma, commented: "We are pleased to partner with Hyloris to bring this product to new markets. This agreement reflects the significant potential of our extended-release ondansetron formulation in addressing unmet needs in oncology support with possible extensions to gastroenteritis and diarrhea-predominant irritable bowel syndrome. We look forward to working with Hyloris as they advance development and commercialization outside North America."

Hyloris will be responsible for further development and regulatory activities in its territories while leveraging RedHill's clinical data from its U.S. development program. This includes pharmacokinetic (PK) trial data[3] and a successful Phase 3 study (GUARD[4]) in patients with acute gastroenteritis and gastritis. Additionally, a positive Phase 2 study for the treatment of diarrhea-predominant irritable

[1] The program name used by RedHill is RHB-102 (with Bekinda® as proposed tradename for the U.S.)
[2] https://www.globenewswire.com/news-release/2024/12/03/2990811/28124/en/Chemotherapy-induced-Nausea-and-Vomiting-Drugs-Industry-Research-Business-Report-2024-Market-to-Surpass-5-Billion-by-2030-Antiemetic-Drug-Formulations-Quality-of-Life-Focus-Drives-.html
[3] A pharmacokinetic (PK) study is a research method used to understand how a drug is absorbed, distributed, metabolized, and eliminated by the body.
[4] The GUARD study was a Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Phase 3 Study to Assess the Safety and Efficacy of RedHill's ondansetron 24 mg for the Treatment of Acute Gastroenteritis & Gastritis. The study was conducted on 321 adults and children over the age of 12 in 21 centres across the U.S. A Confirmatory Phase 3 is still required

bowel syndrome (IBS-D) met its primary endpoint. Building on these existing clinical study results, Hyloris aims to complete the manufacturing and clinical activities for CINV/RINV, targeting market entry by 2028 or earlier through distributors, pending regulatory approvals.

Under the terms of the agreement, Hyloris will pay RedHill a license fee upon signing and upon submission for product approval. Subject to certain cost recoupments by Hyloris, RedHill will be also entitled to performance-based payments which include a share of milestone payments received from distributors (up to a mid-twenties percentage), a low double-digit percentage share of Hyloris' net margin on product sales, and additional milestones contingent upon achievement of ambitious net margin-based targets. Each of these target-based payments are payable only once and cannot exceed a low double-digit percentage of the net margin achieved in any given year.

About Ondansetron ER

Ondansetron ER is a once-daily, patented, bimodal extended-release formulation of ondansetron, designed to provide sustained relief from nausea and vomiting associated with chemotherapy, radiotherapy, and post-operative recovery (CINV/RINV). Ondansetron works by blocking the action of serotonin, a natural substance in the body that can cause vomiting. This mechanism makes it a cornerstone therapy for managing nausea and vomiting in patients undergoing intensive treatments. Ondansetron is currently commonly given as an oral tablet, orally disintegrating tablet, or injection. However, its immediate-release formulation requires multiple daily doses due to its short half-life (~3–5 hours).

This novel formulation is designed to ensure 24-hour symptom control with a single oral tablet, enhancing patient compliance and treatment adherence. The bimodal release mechanism delivers ondansetron in two distinct phases: an immediate-release (IR) component for rapid onset of action and a sustained-release (SR) component to maintain consistent therapeutic levels over an extended period. This controlled-release approach minimizes peak-and-trough fluctuations, reduces side effects, and provides more stable symptom management an improved overall treatment experience for patients.

The global antiemetics drugs market size was valued at USD 7,49 billion in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 5,98% from 2024 to 2030[5]. In 2023, 1,13 billion ondansetron tablets were sold in the targeted territory, an 8% increase over 2022, with total sales reaching USD 388 million, up 13% year-over-year[6].

Beyond oncology and post-surgical applications, ondansetron ER is also being explored for gastrointestinal indications, including gastroenteritis[7], gastritis, and diarrhea-predominant irritable bowel syndrome (IBS-D)[8].

[5] Antiemetics Drugs Market Size & Share Analysis Report 2030, Grandview research
[6] IQVIA
[7] Acute gastroenteritis and gastritis are characterized by inflammation of the mucus membranes of the gastrointestinal tract, most commonly caused by viral infection, with symptoms including nausea, vomiting, diarrhea and abdominal pain.
[8] A Phase 2 study (with Ondansetron 12 mg ER) in IBS-D demonstrated positive results.

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.

The Company's development strategy primarily focuses on leveraging existing regulatory pathways, such as the FDA's 505(b)2 pathway in the U.S or similar regulatory frameworks in other region which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This type of regulatory 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 has built a broad, patented portfolio of 21 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Two products are currently in early phases of commercialization with partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. Outside its core strategic focus, the Company also has 1 approved high barrier generic product launched in the U.S. and 2 high barrier generic products in development.

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

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on U.S. development and commercialization of drugs for gastrointestinal diseases, infectious diseases and oncology.

More information about the Company is available at www.redhillbio.com / X.com/RedHillBio.

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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.

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