Update on Developments Following Completion of Forensic Independent Review with respect to QliniQ Transactions

- Board approved number of governance changes
- Company reacts to the warning issued by the FSMA on 5 July 2024 with respect to the Company

Liège, Belgium – 8 July 2024, 1.30pm CET – Regulated - Inside Information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL) ("**Hyloris**" or the "**Company**"), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today provides an update on the developments since the recent completion of the forensic independent review that was initiated on 29 April 2024.

1. Forensic Independent Review

Hyloris announced on 20 January 2023 that it had successfully concluded agreements regarding (i) the in-licensing by Hyloris from QliniQ BV ("**QliniQ**") of HY-088 and (ii) the divestment by Hyloris to QliniQ of HY-038.

HY-088 is a product candidate targeting hypophosphatemia.[1] It targets a new, improved formulation of a product currently available as a compounded medication in several countries.[2] The agreement with QliniQ provided Hyloris with worldwide rights, with the exception of the Netherlands and certain Middle Eastern and developing countries, where the original licensor retained the rights.

HY-038 is a generic product[3] that Hyloris considered a non-core asset.[4]

These transactions and their accounting treatment were scrutinized by the Belgian Financial Services and Markets Authority ("**FSMA**"). The inquiries from and exchanges with the FSMA initially led the Company to restate its fiscal year 2022 and fiscal year 2023 results in March 2024.[5]

[1] Phosphate deficiency (*hyposphosphatemia*) is a potentially serious medical condition with limited commercially available treatment options. Oral administration is usually the preferred way of treating this condition, although in most countries no approved oral drugs exist. Currently, physicians often rely on compounded drugs which have, by definition, not been submitted for regulatory scrutiny regarding safety, efficacy, and quality (see footnote 2)

[2] Compounded medicines are customized medications prepared by a pharmacist according to a doctor's prescription to meet the specific needs of an individual patient. These medicines are tailored by combining, mixing, or altering ingredients to create a medication that is not commercially available in the desired form or dosage. Compounded medicines have not obtained regulatory approval.

[3] Generics are exact copies of existing medications, while repurposing or reformulation drugs involve finding new uses for existing drugs, requiring additional clinical trials and data for approval.

[4] This divestment was in line with Hyloris' previously announced strategy to no longer actively pursue new activities in the generic space as these are outside of the Company's strategic focus on the 505 (b)(2) regulatory pathway. Since the Company's IPO, limited activities with respect to HY-038 were undertaken as Hyloris was not yet able to identify a suitable CMO (contract manufacturing organization) capable of manufacturing at the desired price.

[5] To reflect that both transactions with QliniQ qualify as a non-monetary exchange under IFRS, because negotiations and valuations regarding HY-088 and HY-038 occurred simultaneously.

In the second half of April 2024, a few days before the annual report for the fiscal year 2023 was due to be published, KPMG replaced its permanent representative for the Company and informed the Company's Audit Committee that additional audit work was required.

Following further exchanges with the Company's auditor and, subsequently, the FSMA, the Company initiated a forensic independent review on the matter in April 2024. On 29 April 2024 the FSMA suspended trading of the Company's shares.

The forensic independent review was carried out by a reputable international law firm as independent legal expert, appointed by and under the supervision of an *ad hoc* committee of independent directors of the Company. The work included a forensic data review concerning the QliniQ transactions, interviews with Hyloris' executive management team concerning the QliniQ transactions, as well as obtaining an independent valuation expert opinion on the purchase price paid for HY-088.

The forensic independent review was completed early June 2024 and the FSMA has informed the market of the key findings in a public communication of 5 July 2024. For more detail on the QliniQ transactions, their accounting treatment, the FSMA's concerns and the key findings of the forensic independent review, reference is made to that communication as well as to the Company's press releases of 20 January 2023, 14 March 2024 and 30 April 2024. For the FSMA's communication, reference is made to section 4 below.

2. Business rationale and development status

a. Hyloris has a broad portfolio of 21 commercialized products and product candidates. Even though HY-088 is a niche product requiring an investment well below Hyloris' average, Hyloris' management team remains highly confident in the strategic value and commercial potential of HY-088 (and affirms that a transaction regarding HY-088 would have been done even in the absence of the HY-038 transaction). In addition, management confirms that, even though the forensic independent review concluded that there are strong indications that the two QliniQ transactions were apparently linked, both transactions were aligned with Hyloris' strategic objectives.

   Management refers to the report of the independent valuation expert which contributed to the forensic independent review and which concludes as follows with regard to the consideration paid for HY-088: "*Based on (i) the limited procedures performed, as described above, on the business plan prepared by Management as of the date of the Transaction, (ii) the use of the generally accepted valuation methods under the income approach, and (iii) pursuant to the conditions and limitations contained herein,* ***it is our preliminary view that nothing leads us to believe that the Transaction Price is not within an acceptable range of preliminary values*****".** The Company notes that the forensic independent review has not conclusively established the absence of substance of the HY-088 and HY-038 transactions.

   Phosphate deficiency affects roughly 5% of hospitalized patients. The presence of lower-quality compounded products in this space indicates an existing market for a more effective solution such as HY-088. Furthermore, market research suggests continued expansion in the phosphate deficiency treatment sector, potentially increasing HY-088's patient reach. Additionally, if Hyloris opts for a U.S. submission, Hyloris will not incur the significant submissions costs under the terms of the agreement. In essence, HY-088 is expected to deliver meaningful benefits to patients and significant value to investors, reinforcing Hyloris' commitment to innovative healthcare solutions.

b. The development of HY-088 remains on track for European market access by the second half of 2026, with the total cost of acquisition and development, including licensing fees and external development expenses, staying (well) under € 2 million as previously announced. After development completion, Hyloris will not incur any further financial obligations to the original developer.[6]

   Development began in late 2022 and by early 2023 an external development company identified candidate formulations through product design planning, ingredient selection activities, and testing. Further work throughout 2023 ensured stability, refinement, and successful lab-scale production. GMP batch manufacturing is anticipated for late 2024

3. Decisions of the Board of Directors

During and after the review process, the Company was formally informed of the executive management team's opinion that the forensic independent review is affected by procedural, methodological and substantive deficiencies. Management disputes the findings and believes *inter alia* that the independent legal expert lacked impartiality, has not considered their explanations and comments properly, and that the findings give an incomplete and distorted picture. The management team also point out that there was regular interaction with the Company's statutory auditor on the accounting treatment of the transactions. Finally, the management team also insists in particular on the actual substance of the HY-038 and HY-088 transactions and reiterates their firm belief that the HY-088 deal will create value for the Company.

In the first half of June 2024, the Board has deliberated on multiple occasions on the findings of the forensic independent review, the recommendations of the *ad hoc* committee (as described in the FSMA communication of 5 July 2024), and the comments by the executive management team. Where appropriate, meetings were held in closed session with non-executive directors only. During this time, the Board was also informed that the Company's CEO has offered to step down as CEO and transition into a dedicated strategy-focused role concentrating on long-term company objectives and direction, and that the Company's CFO and CLO have offered to resign and leave their roles within the Company in mutual consent after an appropriate transition period.

As a result, taking into account a.o (i) the findings of the forensic independent review, (ii) the recommendations of the *ad hoc* committee, (iii) the views of the executive management team (and the abovementioned proposals by the CEO, CFO and CLO to leave their current roles) and (iv) the Company's corporate interest, the Board has taken the following decisions:

- The Company will initiate a transition process to an independent CEO, with a view to the current CEO, Mr. Stijn Van Rompay, assuming a dedicated role focussed on driving and implementing the Company's global strategy. During the interim period, Mr. Thomas Jacobsen (Hyloris' Chief Business Development Officer and co-founder) will be appointed as co-CEO alongside the current CEO and all major decisions shall be made jointly by the co-CEOs.
- Subject to a transition period, Hyloris' CFO and CLO will leave their roles within the Company in mutual consent in the interest of the Company (but without acknowledging any of the principal findings of the review). At the request of the Board, the CFO will remain with the Company to finalize the annual accounts for the fiscal year 2023 and (if needed) the half-year results, and hand over to the new CFO.

[6] Unless Hyloris decides to expand the list of targeted countries with the U.S., in which case a single digit profit participation is due on U.S. sales.

- The Company's governance will be strengthened by (i) having the internal control systems reviewed by an independent third party, (ii) creating an internal audit function, and (iii) implementing written compliance policies and clear internal reporting lines (including to the Audit Committee).

The Company is evaluating continuously how and when these decisions will be implemented considering the corporate interest and the developments in this matter.

4. FSMA Communication

Following the decisions of the Board, the Company has informed the FSMA of the findings of the forensic independent review, the comments of the executive management team, and the Board's decisions. Since then, the Company has had ongoing contacts with the FSMA (including with regard to the content of the press release to be issued concerning the findings of the forensic independent review).

While these contacts were ongoing, on 5 July 2024, the FSMA decided to release a public communication regarding the Company, setting out a.o. the FSMA's views of the QliniQ transactions and stating that the FSMA has serious doubts about the reliability of the information that Hyloris has provided to the market.

The Company has taken note of the FSMA's communication. The Company is of the view that it has made available (and intended to make available through a press release concerning the forensic independent review drafted in consultation with the FSMA) to the public all information that is relevant for investors. As in the past, the Company is committed to inform the market correctly and it will continue discussions with the FSMA in a view to agree on a communication policy which meets the concerns of the FSMA.

5. FY 2023 Annual Accounts - 2024 Annual General Meeting – Going Forward

The Company is working closely with the Company's auditor to finalize the annual accounts for the fiscal year 2023 as soon as possible. The Company will communicate in due course when its 2023 Annual Report will be published, and when its Annual General Meeting will be held.

The Company is also working to achieve resumption of trading of Hyloris' shares as soon as possible. In this respect, reference is made to the FSMA's communication of 5 July 2024 in which the requirement is set out for the Company's 2023 Annual Report and the opinion from the statutory auditor to be published in order for trading of Hyloris' shares to be resumed.

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 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.

Hyloris has built a broad, patented portfolio of 18 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 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.

For more information, contact Hyloris Pharmaceuticals:

Hyloris Pharmaceuticals, Investor Relations and Media
investorrelations@hyloris.com

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, which 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.