Hyloris reports full year results for 2022 & provides business outlook

- Strong R&D progress & attractive commercial deals, including additional Tranexamic Acid RTU out-licensing deals
- Potential U.S. market approval for Maxigesic® IV in H2 2023
- Promising new product candidates driving innovation and on track for a planned acceleration towards a portfolio of 30 assets before 2025
- Revenues of €3 million, net loss decreased to €10.8 million with increased R&D expenses
- €43 million in cash & cash equivalents, no financial debt
- Webcast at 1PM GMT / 2PM CET/ 9AM EST (register here)

Liège, Belgium – 15 March 2023 – 7PM CET – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces its financial and operational results for the year ending on 31 December 2022, as well as its business outlook for 2023 and beyond.

Stijn Van Rompay, chief executive officer of Hyloris, commented: *"Our strategy is as successful as it is unique, and 2022 and early 2023 has proven this once again. In an exceptionally difficult year for both the financial markets and the healthcare sector, we successfully raised €15 million and announced HY-083, a product candidate targeting idiopathic rhinitis. This was followed in early 2023 by the in-licensing of a product candidate targeting hypophosphatemia. Other pipeline assets progressed at a rapid pace and are well underway to providing real solutions to unmet medical needs in the upcoming years."*

"Several clinical trials will be conducted over the course of 2023 and our team is paving the way to a market authorization for Maxigesic® IV in the U.S. before year-end," Van Rompay continued. *"Our headcount grew from 21 at the end of 2021 to 39 today, nearly doubling in size and adding tremendous amounts of expertise throughout our business. Thanks to proactive cost and cash management and sufficient cash to support the current portfolio, Hyloris is geared for an acceleration of its strategy with an increased focus on repurposed products bringing more value to underserved patient populations and Hyloris shareholders. We reviewed around 200 opportunities in 2022 and aim to grow the portfolio to 30 product candidates and marketed products before 2025. I am excited about the opportunities we are currently evaluating and eager to disclose new deals to our shareholders in the near future."*

New product candidates added to the pipeline

HY-083 was announced in November 2022. This novel, proprietary formulation will be administered intranasally to treat idiopathic rhinitis. Idiopathic rhinitis is a medical disorder characterized by a nasal symptoms that resemble nasal allergies and hay fever (allergic rhinitis) but are not related to a known cause like allergens or infectious triggers.

Idiopathic rhinitis features an overexpression of TRPV1-receptors in the nasal mucosa giving rise to nasal obstruction (a stuffy nose), rhinorrhea (a runny nose) and sneezing, chronically affecting quality of life in patients. Our product candidate aims to activate and depolarize these receptors in the nose.

An estimated 7% of the world population is affected by idiopathic rhinitis, representing an estimated 19 million people in the U.S. alone. 13% of them have moderate to severe idiopathic rhinitis, leading

them to actively seek out specialist care. Hyloris seeks to offer a new, unique, safe and approved targeted therapy treatment option.

HY-088 was announced in January 2023, the Company in-licensed the technology to develop development of an oral liquid targeting hypophosphatemia, a mineral deficiency in the blood. In severe forms, this condition can be life threatening. The condition can result in muscle and bone weakness, respiratory or heart failure, seizures or coma amongst others.

There is a wide range of underlying conditions leading to hypophosphatemia which could be hereditary (such as X-linked hypophosphatemia, hypophosphatemic rickets, osteomalacia, Cushing syndrome) or acquired (anorexia nervosa, recovery phase of diabetes-related ketoacidosis, alcohol withdrawal, respiratory alkalosis, long term use of diuretic and phosphate binders).

Chronic hypophosphatemia can become life threatening, making direct treatment of the hypophosphatemia desirable in cases where treating the underlying condition does not solve the mineral deficiency.

It is estimated hypophosphatemia affects around 5% of hospitalized patients, and a subpopulation needs direct treatment during and/or after their hospital stay.

Treatment protocols for patients deficient in phosphate are well-established and have proven useful in other situations of bone mineral imbalance. Oral administration is the preferred way of treating hypophosphatemia, although in most countries no approved drugs exist. Currently, physicians mostly rely on compounded drugs which have, by definition, not been submitted for regulatory scrutiny regarding safety, efficacy, and quality.

Further commercial roll-out

Maxigesic® IV, a unique combination of paracetamol and ibuprofen used for post-operative non-opioid pain management, is currently licensed to partners covering over 100 countries across the globe.

During 2022 and early 2023:

- A Complete Response Letter from the United States Food and Drug Administration (FDA) was received, stating that it was unable to complete its review, requesting additional information relating to potential leachable and extractable compounds expected to be present in the drug product based on the drug product packaging. Importantly, the agency did not report any issues related to the data generated during the clinical development program.
- Hyloris and its partners believe to be able to address the recommendations made and resubmit Maxigesic® IV before the summer of 2023 with a potential New Drug Application (NDA) approval by the end of 2023. The non-opioid analgesic space and the market for post-operative pain is growing rapidly and is forecasted to reach $1.7 billion in 2028 in the U.S., up from $745 million in 2019.[1]
- Submissions were made in 15 countries in Asia, Africa and Latin America, including large pharmaceutical markets such as Canada and Mexico.

[1] DelveInsight Market Research Report (2020)

- Marketing authorizations have been granted in several countries including Italy, Norway, Indonesia, The Netherlands, Finland, Singapore and Hong Kong.
- Launches occurred in 7 countries including Denmark, Sweden, Finland, Norway and The Netherlands. Imminent launches are expected in several additional countries, bringing the total number of countries where Maxigesic® IV will be available up to more than 20.
- 4 U.S. patents were granted to Hyloris, ranging in expiry between 2035 and 2039.

Sotalol IV is a novel, intravenous, patented, IV formulation of Sotalol for the treatment of atrial fibrillation and life-threatening ventricular arrhythmias developed for the U.S. market. In 2022 further commercial efforts were made to accelerate commercial roll-out, inclusion in hospital drug formularies and clinical education of hospital staff.

Other commercial highlights

Tranexamic Acid RTU

Out-licensing agreements were signed in early 2023, covering an important European country and a major Southeast Asian country, with a combined population of over 60 million people. Earlier agreements have been signed in 2021 for Australia, New-Zealand and Canada.

In doing so, the Company confirms its strategy to out-license near the end of the product development and to prioritize downstream revenue of the product candidates over upfront milestone payments. Regulatory submission in the partnered territories is expected within 2023, and additional out-licensing agreements are expected, going forward.

Thomas Jacobsen, chief business development officer of Hyloris, commented: *"Thanks to recent out-licensing deals, the previously untapped global potential of tranexamic acid RTU was brought further into view. We now believe the future sales volume for tranexamic acid RTU outside of the United States could outpace the future sales volume within the U.S."*

Tranexamic acid RTU is an antifibrinolytic drug. By inhibiting the fibrinolysis, tranexamic acid promotes the formation of blood clots

HY-038

In December 2022, the Company out-licensed HY-038, a generic and non-core asset for an out-licensing fee of €1 million. In doing so, Hyloris highlighted its increased focus on repurposed product candidates which offer a bigger difference in patient outcomes, as well as a higher expected return on investment.

Cardiovascular portfolio

in Q4 of 2022, Hyloris and its development partner API renegotiated specific commercial agreements. As a consequence, no further royalties are payable on Sotalol IV to API, except if the in-market net product sales exceed USD 100 million. As part of renegotiation of commercial terms, the Company made prepayments of expected future royalties amounting to $0.7 million.

R&D update

In 2022, R&D activities have progressed on all fronts, bringing our range of 14 product candidates and 3 high-barrier generic products closer to market in different ways, following in the footsteps of 2

products which are already marketed today. Some development timelines were impacted by the Covid19-pandemic and the required transfer of manufacturing activities to alternative third-party manufacturers. Multiple discussions are being held with regulatory agencies and partners to confirm and validate development plans.

A new and improved R&D lab is under construction at Légiapark in Liège (Belgium), where our head office moved after the summer of 2022. This will allow the Company to perform drug formulation and analytical activities in-house for its growing pipeline, further streamlining processes and more effectively deploying internal resources.

Cardiovascular portfolio

In its entirety, the cardiovascular portfolio covers a broad range of indications in the biggest therapeutic segment globally. With products advancing through or towards the clinical study phase, Hyloris expects to make impactful differences in patients' lives.

Main highlights for 2022 and expected milestones for 2023 include:

Aspirin IV: The clinical phase of the study assessing the pharmacokinetics has been completed in 2022. Preliminary data has shown faster onset and good tolerability of Aspirin IV with more analytical work required. An additional clinical study is under preparation.
A strategic review led to a change in the contract manufacturing organisation (CMO) for the manufacture of registration batches for the New Drug Application (NDA).
Aspirin IV is an intravenous (IV) formulation of acetylsalicylic acid (ASA). Aspirin is not available in the U.S. as an IV product.

Milrinone: Hyloris has contracted a CDMO for development and manufacturing. A successful Type C meeting with the FDA was concluded, confirming development plans for a novel, extended-release formulation offering convenient oral dosing for a selected population of end-stage heart failure (HF) patients.

HY-074: The FDA has confirmed the development of the proposed formulation can be pursued. Hyloris is preparing for the manufacturing of validation and registration batches. Non-clinical work is expected to finish before H2 of 2023.

HY-074 is an intravenous formulation of current standard of care treatment for acute coronary syndrome (ACS) to offer faster onset of action (and thereby potentially reducing the risk of death), more convenient administration (more notably in patients who are nauseated or unconscious), and dosage control. It is currently available in oral form, which should allow for an optimal switching strategy from the oral form to an IV.

Dofetilide IV: Both formulation development and non-clinical studies have been successfully completed. A new CMO was contracted to ensure reliable development and supply, hereby incurring a delay as a consequence of the transfer.

Other Value-Added Programs

Our added-value programs are progressing well. Several discussions are ongoing with regulatory agencies to confirm and validate development plans.

Main highlights for 2022 and expected milestones for 2023 include:

Tranexamic Acid Oral Mouth Rinse (previously HY-004): Positive Phase 1-results showed that HY-004 was found to be well-tolerated under varied conditions with no serious adverse events following tooth extraction. Hyloris also plans to investigate its use for broader related indications in patients undergoing oral surgical procedures with or without bleeding disorders that would benefit from a locally acting antifibrinolytic agent. Recruitment for a Phase 3 study will have started before H2 of 2023.

Miconazole/Domiphen Bromide: Recruitment for the phase 2 clinical trial is completed and last patient last visit (LPLV) will have occurred by Q2 2023. The results of this Phase 2 study will guide the Company for the preparation and design of the next clinical trial.

Hyloris is co-funding the development of Miconazole/Domiphen Bromide, a topical synergistic combination treatment for Recurrent Vulvovaginal Candidiasis (rVVC), a chronic and debilitating vaginal infection commonly caused by the yeast Candida albicans. This condition affects nearly 10% of women during their lifetime. MCZ/DB has a strong scientific and business rationale.

Alenura™: Multiple clinical trials are expected to start throughout 2023, including a four-arm Phase 2, prospective, randomized, double-blind, placebo-controlled, multi-center, single-dose, pharmacodynamic study comparing Alenura™ to its 2 individual components (alkalinized lidocaine and heparin) as well as placebo.

Alenura™, is a first-line drug treatment for acute pain in interstitial cystitis/bladder pain syndrome (IC/BPS), a condition affecting at least 6 million people in the U.S. Alenura™ is a patented, innovative, clinical-stage bladder instillation product candidate that combines lidocaine in a new alkalinized form with heparin. Thanks to the novel dual mode-of-action, Alenura™ has the unique potential to i) immediately relieve pain, and ii) augment the mucous inner layer of the bladder wall.

Plecoid Agents: The definition of the preferred formulation has progressed significantly in anticipation of clinical trials.

These chelating agents could improve the effectiveness of existing chemotherapy in patients with acute myeloid leukemia (AML) and small cell lung cancer (SCLC). Previous studies suggested that elevated levels of toxic metals are associated with inferior survival in patients with AML (160.000 patients globally).

Atomoxetine oral liquid: An innovative taste masking strategy was deployed, targeting a preferred taste for young patients, following FDA feedback.

Atomoxetine is used primarily for the treatment of patients with attention deficit hyperactivity disorder (ADHD). This product candidate allows for improved dosing (as patient specific dosing is also in part based on body weight) and convenience. Other oral liquid products in this therapeutic segment have captured significant market share in competition with oral solids, underlining the need for a (novel) oral liquid formulation of Atomoxetine.

HY-029: A successful pilot study demonstrating bioequivalence was completed in 2022. A pivotal study can be expected to start in H2 of 2023. Industrial batch manufacturing has been conducted to

demonstrate pharmaceutical quality of the medicinal product and robustness of the manufacturing process.

HY-029 is a liquid formulation of an existing antiviral drug that is currently only available in oral solid form.

Management & Board changes

Both the C-level executives and all board members remained in their respective positions, providing continuity in the company's leadership.

Business Outlook

With 16 reformulated and repurposed molecules, and 3 high-barrier generics, several clinical trials are expected to start and/or finish within 2023.

The Company aims to accelerate growth of the product pipeline, with the end goal of reaching 30 product candidates before 2025.

Assuming continued strategic out-licensing, commercial success for Maxigesic® IV and Sotalol IV, additional non-dilutive funding and milestone payments, the Company believes it is sufficiently capitalized to execute the full development of the current pipeline assets (14 product candidates, 3 generics and 2 commercial products).

Webcast details

The Company will host a webcast conducted in English to present its 2022 annual results and 2023 Business Outlook, followed by a live Q&A session. The webcast will start on March 16th 2023 at 2PM CET / 1PM GMT / 9AM EST. To join the webcast, please register at Hyloris.com/webcast

FINANCIAL HIGHLIGHTS 2022

	Year ended 31 December		
(in € thousand)	**2022**	**2021**	**Variance**
Revenues	**2.951**	**3.096**	**-4,7%**
Cost of sales	(94)	(107)	
Research and development expenses	(10,151)	(5,056)	**100,8%**
General and administration expenses	(3,517)	(2,900)	**21,3%**
Shares' issuance related expenses	-	-	
Earnings/losses from Associates and joint ventures	(130)	(191)	**-31,9%**
Other operating result	303	(5,381)	
Operating result	**(10,638)**	**(10,541)**	**0,9%**
Net financial result	(127)	(741)	**-82,9%**
Income Taxes	(4)	(297)	**-98,7%**

Result for the period	**(10,770)**	**(11,579)**	**-7,0%**
Net operating cash flow	**(13,154)**	**(11,250)**	**16,9%**
Cash and cash equivalents	**43,457**	**50,012**	**-13,1%**

Financial Review 2022

Income statement

In 2022, total revenues remained stable around €3 million, driven by increased royalties received for Maxigesic® IV and Sotalol IV, the out-licensing agreement of €1 million for HY-038 with QliniQ, IP and regulatory services rendered to development partners.In 2021, most revenue was comprised of one-time milestone payment (€1.8 million) related to Maxigesic® IV.

Research and development expenses increased to €10.15 million in 2022 versus €5.06 million in 2021, in line with several product candidates maturing from early to late-stage development, as well as the expansion of the number of product candidates and increased headcount of the research and development team.

Total general and administrative expenses amounted to €3.52 million versus €2.90 million last year and is mainly explained by additional communication and legal/HR costs. The company remains focus on strong cost and cash management.

As a result, Hyloris closed 2022 with an operating loss of €10.64 million. This was mainly driven by increased R&D expenses for supporting the development of the portfolio.
The net financial loss in 2022 was €0.13 million. Financial income amounted to €0.47 million, comprising mostly a net currency gain of €0.40 million and interest received on deposits of €0.07 million, versus €0.03 million last year.

Financial expenses amounted to €0.59 million versus €0.77 million in 2021 and comprised mostly the impact of the interest rates renegotiation of the shareholder loans, bank interest expenses, currency losses and bank fees. In 2022, Hyloris successfully renegotiated the terms of the shareholder loans, resulting in lower interest rates.

As a result, net losses in 2022 decreased to €10.77 million versus €11.58 million in 2021.

Statement of financial position

The Company's non-current assets mainly consist of (1) investments in joint ventures of € 3.9 million at year-end 2022, (2) intangible assets of €3.6 million at year-end 2022 including capitalized development, purchased assets and in-licensing costs, versus €2.94 million in 2021, (3) the conversion of the loan to Pleco into shares of €1.0 million, (4) a prepayment of future royalties to API of $0.7 million and (5) a tax credit. Hyloris does not capitalize research and development expenses until the filing for a marketing authorization for the applicable product candidate. Research and development expenditures incurred during the

period were accounted for as operating expenses. When an intangible asset is acquired and capitalized, the amortization begins when the asset is available for commercialization.

The Company's current assets mainly consist of €43.46 million in cash and cash equivalents on total assets of €61.86 million, and trade and other receivables of €5.13 million which mainly consist of services rendered to partners, milestones from AFT related to Maxigesic and out-licensing revenue (€1.0 million) from Qliniq.

In 2022, Hyloris raised an amount of €15 million in gross proceeds via an accelerated bookbuild, offering 967,742 new shares, the capital and share premium increased with respectively €6 thousand and €2.83 million through the exercise of 1,200,000 outstanding transactions warrants leading to company's equity amounted to €55.04 million.

By year-end all shareholder loans were repaid, making the Company free of any financial debt on 31 December 2022. The same shareholders expressed their conditional willingness to support the Company with a renewed shareholder loan in the future if needed.

Cash flow statement

Net cash outflow from operating activities was €13.15 million in 2022, compared to €11.25 million in 2021. As part of renegotiation of commercial terms, the Company made prepayments of expected future royalties amounting to $0.7 million to API.

Net cash outflow from investing activities was €1.24 million in 2022, compared to €3.08 million in 2021, and mainly related to investments in joint ventures, capital expenditure and capitalization of development expenses.

The financing activities amounted to a net cash inflow of €7.84 million in 2022 compared to a net cash outflow of €0.06 million in 2021 mainly driven by the net proceeds from the private placement via an accelerated bookbuild for net proceeds of €14.34 million, proceeds from the execution of transaction warrants for €2.83 million and the reimbursement of the shareholder loans for €9.28 million including accumulated interest.

Consequently, the cash and cash equivalents amounted to €43.46 million end of 2022 versus €50.01 million at the end of 2021.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION FOR THE YEAR ENDED DECEMBER 31

ASSETS (in thousands of euros)	31-Dec-22	31-Dec-21
Non-current assets	***11,063***	***9,485***
Intangible assets	3,607	2,944

Property, plant and equipment	176	122
Right-of-use assets	885	173
Equity accounted investments	3,948	4,079
Other investment, including derivatives	1.000	453
Trade and other receivables	1.447	1.714
Current assets	***50,801***	***53,959***
Trade and other receivables	5,127	2,321
Other investment, including derivatives	469	528
Prepayments	1,748	1,098
Cash and cash equivalents	43,457	50,012
TOTAL ASSETS	**61,863**	**63,444**

EQUITY AND LIABILITIES (in thousands of euros)	**31-Dec-22**	**31-Dec-21**
Equity	***55.045***	***48.056***
Share capital	140	129
Share premium	121,513	103,693
Retained earnings	(53,476)	(43,226)
Result of the period	(10,770)	(11,579)
Share based payment	1.621	2.391
Cost of Capital	(4,460)	(3,827)
Other reserves	476	476
Non-current liabilities	**1.047**	**409**
Borrowings	747	109
Other financial liabilities	300	300
Current liabilities	**5,772**	**14,978**
Borrowings	138	65
Other financial liabilities	3,212	11,815
Trade and other liabilities	2,422	2,749
Current tax liabilities	-	349
TOTAL EQUITY AND LIABILITIES	**61,863**	**63,444**

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED DECEMBER 31

in € thousands	**2022**	**2021**
Revenue	2,951	3,096
Cost of sales	(94)	(107)
Gross profit	**2,857**	**2,988**
Research and development expenses	(10,151)	(5,056)
Selling, general and administrative expenses	(3,517)	(29)

Share of result of equity-accounted investees, net of tax	(130)	(191)
Other operating income	315	389
Other operating expenses	(12)	(5.770)
Operating profit/(loss) (EBIT)	**(10,638)**	**(10,541)**
Financial income	466	32
Financial expenses	(594)	(773)
Profit/(loss) before taxes	**(10,766)**	**(11,282)**
Income taxes	(4)	(297)
PROFIT/(LOSS) FOR THE PERIOD	**(10,770)**	**(11,579)**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED DECEMBER 31

	Attributable to equity holders of the Company						
			Other reserves				
(in thousands of euros)	Share capital	Share premium	Share-based payment reserve	Cost of Capital	Other reserves	Retained earnings	Total Equity
Balance at December 31, 2021	**129**	**103,693**	**2,391**	**(3,827)**	**476**	**(54,805)**	**48,056**
Private Placement Via an Accelerated Bookbuild Offering	5	14,995		(634)			14,366
Equity Transaction via Transaction Warrants	6	2,826	(1,329)			1,329	2,832
Share-based payments			560				560
Total comprehensive income						(10,770)	(10,770)
Balance at December 31, 2022	**140**	**121,513**	**1,622**	**(4,460)**	**476**	**(64,246)**	**55,045**

CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31

in € thousands	**2022**	**2021**
CASH FLOW FROM OPERATING ACTIVITIES		
Net result	(10,770)	(11,579)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation, amortisation and impairments	196	137
Share-based payment expense	560	576
Derivatives financial instruments	52	-
R&D Tax Credit	(315)	-
Interest expenses on shareholders loans	164	-
Loss on drecognition of shareholders loans	486	198
Equity transaction costs	29	-
Losses from Associates and joint ventures	130	191
Losses on disposal of PPE	16	
Other non-cash adjustments	16	(1)
Changes in working capital:		
Trade and other receivables	(2,230)	(2,068)

Other investment, including derivatives	(27)	(1,627)
Prepayments	(650)	856
Trade and Other liabilities	(468)	
Other current and non-current liabilities	-	2.063
Cash generated from operations	**(12,812)**	**(11,253)**
Interest paid	7	3
Income Taxes paid	(349)	
Net cash generated from operating activities	**(13,154)**	**(11,250)**
CASH FLOW FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(101)	(107)
Purchases of Intangible assets	(638)	(954)
Proceeds from disposal of intangible assets	-	219
Acquisition of Other Investments	(500)	(21)
Investments in associates and joint ventures	-	(1,270)
Repayment received from other financial assets	-	216
Payment of other financial assets	-	(1,157)
Discontinued operations		
Net cash provided by/(used in) investing activities	**(1,239)**	**(3,075)**
CASH FLOW FROM FINANCING ACTIVITIES		
Reimbursements of borrowings and other financial liabilities	(7,376)	
Reimbursements of lease liabilities	(79)	(62)
Proceeds from other non-current liabilities	0	-
Proceeds from Private Placement via ABB	14,337	-
Proceeds from Execution Transactions Warrants	2,832	-
Interests paid	(1,877)	-
Net cash provided by/(used in) financing activities	**7,838**	**(62)**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(6,555)**	**(14,387)**
CASH AND CASH EQUIVALENTS at beginning of year	50,012	64,399
CASH AND CASH EQUIVALENTS at end of year, calculated	43,457	50,012

Audit Report

The statutory auditor, KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises, represented by Olivier Declercq, has confirmed that the audit procedures, which have been substantially completed, have not revealed any material misstatement in the accounting information included in the Company's annual announcement.

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 16 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 https://hyloris.com/ and follow us on LinkedIn.

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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.