Hyloris Pharmaceuticals Broadens Pipeline with a Proprietary Intranasal Product Candidate of a TRPV1[1] agonist (HY-083) for Idiopathic Rhinitis

- Hyloris targets a condition that affects up to 7% of the global adult population without any satisfactory treatment currently available

- The addition of this new value-added product candidate brings Hyloris toward its goal of 30 assets before 2025

Conference call Wednesday November 23rd at 4PM CET/10AM EST (details below)

Liège, Belgium – 22 November 2022 – 6PM CET – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announced the development of a new proprietary formulation – a TRPV1 agonist - administered intranasally as a spray, to treat idiopathic rhinitis.

Idiopathic rhinitis is a medical disorder characterized by a collection of nasal symptoms that resemble nasal allergies and hay fever (allergic rhinitis) but are not caused by a known cause like allergens or infectious triggers. Idiopathic rhinitis features an overexpression of TRPV1 in the nasal mucosa giving rise to nasal obstruction, rhinorrhoea (colloquially: a runny nose), and/or sneezing.

Hyloris' treatment approach is to activate and depolarize TRPV1 receptors leading to restoration of a normal function of the nasal mucosa. Current treatment options for idiopathic rhinitis are not consistently successful. This leads to unnecessary and often ineffective surgery for severe cases, such as nasal septal corrections and/or inferior turbinate reductions.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"We are pleased to announce another value-added product candidate to add to our portfolio of programs. This proprietary intranasal product candidate with a well-known mechanism of action should solve a large unmet medical need and offer patients rapid and sustainable relief."*

"Our focused strategy to acquire new value-added product candidates has brought us closer to our goal of reaching 30 assets in our portfolio before 2025. This has solidified our positioning to be a market leader in the development of value-added product candidates utilizing the expedited and cost-effective 505(b)2 regulatory strategy in the U.S. We aim to develop a low-dose application that can be administered locally via a nasal spray first in Europe before pursing global roll-out."

Peter Hellings, Full Professor at the University of Leuven, Belgium, and Chair of EUFOREA (European Forum for Research and Education in Allergy and Airways diseases), commented: *"Idiopathic rhinitis is a burdensome condition of the nasal mucosa with no satisfactory medical or surgical treatment, where attempted symptom management fails in nearly all cases. It is a chronic condition associated with interrupted sleep, irritability and poor concentration. Hence, it can be a severe detriment to quality of life and capacity to work."*

"Current treatment tries to combine an antihistamine and an intranasal corticosteroid used in other rhinitis types which has yielded only poor results. For severe cases, patients often turn to surgery

[1] TRPV1 is Transient Receptor Potential cation channel subfamily V member 1. The function of TRPV1 is detection and regulation of body temperature. In addition, TRPV1 provides a sensation of scalding heat and pain (nociception)

which is not a cure either. Our strategy is to defunctionalize the overactivated sensory nerve fibres by a targeted, local acting medicinal product and present clinical evidence of efficacy and safety."

CONFERENCE CALL

Hyloris will host a conference call on Wednesday November 23rd at 4PM CET/10AM EST, in attendance of Prof. Dr. Peter Hellings. The webcast may be accessed via Microsoft Teams using the following details or by clicking here.

Join on your computer or mobile app
Meeting ID : 320 762 272 784
Passcode : 3VU5RS

Or call in (audio only)
+32 4 290 22 87
Phone Conference ID: 151 901 636#

About Rhinitis

Rhinitis is defined as the presence of at least one of the following symptoms for more than 1 hour per day: nasal congestion/obstruction, rhinorrhoea, sneezing, and nasal itching.

Chronic rhinitis can be divided into 3 phenotypes: allergic, infectious and non-allergic/non-infectious. For allergic and /infectious rhinitis, current medicinal products are available such as decongestant spray/tablets, antihistamines or corticosteroids.

Idiopathic rhinitis is the largest group within the non-allergic/non-infectious rhinitis group. It occurs in around 7% of the total population, representing an estimated 19 million people in the US alone. 13% of them have moderate to severe idiopathic rhinitis, leading them to actively seek specialist treatment and, who can not provide consistent treatment with the currently available therapy options.

These patients typically live through several years of failed treatment options, adding frustration and wasted expenses to the medical symptoms impacting their quality of life. Rapid relief through a nasal spray should reduce overall treatment costs, improve quality of life and make potentially unsuccessful surgical procedures redundant.

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 payors. Hyloris has built a broad, patented portfolio of 14 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 four high barrier generic products in development. Two products are currently in initial phases of commercialization 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 www.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 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.