pharma& Announces Health Canada has Accepted into Review the Supplement to a New Drug Submission (SNDS) for Pegasys® (peginterferon alfa-2a), for the treatment of polycythaemia vera (PV) and essential thrombocythaemia (ET)

- Pending approval, potential for marketing authorization in or before December 2026

Intended for the Healthcare Media

Vienna, Austria, March 5, 2026 – pharmaand GmbH (pharma&) announced that Health Canada has accepted into review the Supplement to a New Drug Submission (SNDS) for Pegasys (peginterferon alfa-2a) as treatment of the myeloproliferative neoplasms (MPNs), polycythaemia vera (PV), and essential thrombocythaemia (ET).[i] Health Canada's acceptance is based on extensive evidence from scientific and clinical studies, including a Phase 3 multicenter trial (MPD-RC 112, NCT01259856) and a Phase 2 multicenter trial (MPD-RC 111, NCT01259817) conducted by the Myeloproliferative Disorders Research Consortium (MPD-RC), both of which have been published in peer-reviewed journals in 2022 and 2019.

"We are pleased that Health Canada has accepted the Supplement to a New Drug Submission for Pegasys. This review is an important milestone in our effort to bring this treatment to eligible patients in Canada diagnosed with polycythaemia vera or essential thrombocythaemia," said Elmar Zagler, Co-Founder and Managing Director of pharma&. "We appreciate the opportunity to work with Health Canada in the coming months as they review the application to support this pending label expansion."

MPNs, including PV and ET, are clonal disorders that originate from the acquisition of somatic mutations in hematopoietic stem cells (HSCs) and cause overproduction of blood cells. In North America, the incidence of PV is 2.8 per 100,000 among men and 1.3 per 100,000 among women, with a prevalence of 22 cases per 100,000.[ii] In North America, the incidence of ET is 1 – 2.5 per 100,000, with a prevalence of 9 – 24 cases per 100,000.[iii,iv] In both PV and EV, the medial survival is between 15-18 years, exceeding 35 years in younger patients (~≤40 years) when treated.[v,vi] From the Canadian Perspective, PV incidence rates are notably elevated in the province of Quebec compared to the Canadian average. Elevated incidence of PV was also observed in Manitoba, Saskatchewan, Alberta, and British Columbia [vii]

Pending Health Canada's approval of the submission, pharma&'s Canadian subsidiary, Postera Inc., will be responsible for promoting peginterferon alfa-2a in Canada.

In 2019, F. Hoffmann La Roche AG (Roche) announced that it would cease commercializing Pegasys globally. pharma& acquired the global rights to Pegasys in 2021 from Roche to ensure continued access to this treatment and continuity of care for eligible patients. Following the acquisition, pharma& committed to investing in bio-manufacturing capabilities at pharma&'s wholly owned manufacturing plant subsidiary, Loba biotech GmbH. This significant investment

was essential for the new plant to produce the active pharmaceutical ingredient (API) in Pegasys.

Peginterferon alfa-2a is a type I interferon. Interferons (INFs) are a group of cytokines that have a host of immunomodulatory, antiproliferative, and antiangiogenic properties, and were initially named for their ability to "interfere" with viral replication. In myeloproliferative neoplasms, such as PV, studies have shown that IFNs have preferential activity against the hematopoietic stem cell clone, inducing molecular responses and even potential remissions in some treated patients.[viii]

Peginterferon alfa-2a Canadian authorized use and Important Safety Information

Healthcare Professionals should refer to the Canadian Product Monograph for peginterferon alfa-2a available in English and French via this link: https://apcipharma.com/produit/pegasys/, or the Health Canada Drug Product Database at https://health-products.canada.ca/dpd-bdpp/.

In Canada, peginterferon alfa-2a is indicated for:

Chronic Hepatitis C (CHC)

Peginterferon alfa-2a is indicated for the treatment of Chronic Hepatitis C in:

- Adult patients without cirrhosis
- Adult patients with compensated cirrhosis

including HCV/HIV co-infection patients with stable HIV disease with or without antiretroviral therapy.

Chronic Hepatitis B (CHB)

Peginterferon alfa-2a is indicated for the treatment of both HBeAg-positive and HBeAg-negative chronic hepatitis B in:

- Patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic disease).

Geriatrics (> 65 years of age): Clinical studies of peginterferon alfa-2a alone or in combination with COPEGUS did not include sufficient numbers of subjects aged 65 or over to determine whether they respond differently from younger subjects.

Pediatrics (< 18 years of age): Peginterferon alfa-2a is not authorized for use in children and adolescents under the age of 18 years.

Patients and healthcare professionals should be aware that peginterferon alfa-2a is not appropriate for all individuals. Use of this medication is associated with important risks that must be considered alongside its potential benefits.

Contraindications: Peginterferon alfa-2a should not be used in patients with known hypersensitivity to peginterferon alfa-2a, to alpha interferons, to E. coli-derived products, to polyethyleneglycol, or to any component of the formulation. It is also contraindicated in

individuals with autoimmune hepatitis, decompensated cirrhosis, HIV-HCV patients with cirrhosis and a base-line Child-Pugh score ≥ 6, with a history of autoimmune disease, neonates and infants, who have a pre-existing severe psychiatric condition or a history of a severe psychiatric disorder, who have pre-existing thyroid abnormalities for which thyroid function cannot be maintained in the normal range by medication, and in women who are breast feeding.

Serious Warnings and Precautions: Alpha interferons, including peginterferon alfa-2, cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Patients with persistently severe or worsening signs or symptoms of these conditions should be withdrawn from therapy. In many cases, but not all cases, these disorders resolve after stopping interferon therapy. Use with caution in individuals with relevant comorbidities, as outlined in the Product Monograph.

Common Adverse Reactions: The most frequently reported adverse reactions include flu-like symptoms such as unusual tiredness, fever, chills, muscle aches, joint pain, and headaches, which were generally mild to moderate in severity. Additional adverse reactions are described in the Adverse Reactions section of the Product Monograph.

Drug Interactions: Caution is advised when peginterferon alfa-2a is used with Methadone, Theophylline, Telbivudine, and sho-saiko-to, a Chinese herbal medicine, also known as Xiao-Chai-Hu, as interactions may increase the risk of adverse effects or reduce therapeutic efficacy.

Use in Specific Populations: Safety and effectiveness have not been established in pediatric, pregnant, breastfeeding or geriatric populations unless otherwise specified in the Product Monograph.

For **complete risk information**, including detailed contraindications, warnings, precautions, and adverse reactions, please consult the **Product Monograph.**

Healthcare professionals should report any suspected adverse reactions via their national reporting system.

For medical information inquiries outside of the U.S., contact pharma& at mailto:medinfo@pharmaand.com.

About pharma& (pharmaand.com)

pharmaand GmbH (pharma&), a privately owned global company, aspires to breathe new life into proven medicines. The Company is dedicated to preserving the availability and fostering the further development of essential medicines worldwide to leave no patient behind. Since its inception, pharma& has acquired and integrated 10+ medicines, expanding its portfolio across a wide range of therapy areas, with an increasing focus on hematology and oncology treatments. The Company's unique synthesis of subsidiaries, joint ventures, and partners enables

pharma& to provide its portfolio of medicines to eligible patients worldwide by spanning the continuum of research and development, in-house product and active pharmaceutical ingredients (API) manufacturing, distribution via its global partner network, healthcare provider engagement, patient safety services, and patient access services through U.S. Market Access.

pharma& cautions that any forward-looking statements or projections made, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. pharma& does not undertake to update or revise any forward-looking statements

###

pharma& Media Contact:
media@pharmaand.com

References

[i] Health Canada Screening Acceptance Letter dated 25 Feb 2026.

[ii] Leukemia & Lymphoma Society. FS13 Polycythemia Vera Facts. 2015.

[iii] Srour SA, Devesa SS, Morton LM, et al. Incidence and patient survival of myeloproliferative neoplasms and myelodysplastic/myeloproliferative neoplasms in the United States, 2001-12. Br J Haematol. 2016;174(3):382-396

[iv] Meier B, Burton JH. Myeloproliferative Disorders. Hematol Oncol Clin North Am. 2017;31(6):1029-1044.

[v] Tefferi A, Barbui T. Polycythemia vera: 2024 update on diagnosis, risk-stratification, and management. Am J Hematol. 2023 Sep;98(9):1465-1487.

[vi] Tefferi A, et al. Essential thrombocythemia: 2024 update on diagnosis, risk-stratification, and management. Am J Hematol. 2023 Sep;98(9):1465-1487

[vii] Le M, Ghazawi FM, Rahme E, Alakel A, Netchiporouk E, Savin E, Zubarev A, Glassman SJ, Sasseville D, Popradi G, Litvinov IV. Identification of significant geographic clustering of polycythemia vera cases in Montreal, Canada. Cancer. 2019 Nov 15;125(22):3953-3959.

[viii] How J and Hobbs G. Interferons as the First Choice of Cytoreduction in Essential Thrombocythemia and Polycythemia Vera. Journal of the National Comprehensive Cancer Network: JNCCN 2022, 20 (9), 1063–1068. DOI: 10.6004/jnccn.2022.7026.