pharmaand GmbH Receives Positive CHMP Opinion for Pegasys® as a treatment for all eligible patients with polycythemia vera (PV) or essential thrombocythemia (ET)

- European Commission approval decision expected in the coming months.

Intended for the Media

Vienna, Austria, July 1, 2024– pharmaand GmbH (pharma&) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of a Type II variation for Pegasys® (peginterferon alfa-2a), as a treatment for all eligible patients with polycythemia vera (PV) or essential thrombocythemia (ET). Pegasys is currently approved by the EMA for the treatment of chronic hepatitis B (CHB) in adults and children aged 3 years and older or chronic hepatitis C (CHC) in adults and children aged 5 years and older in combination with other medicinal products. However, Pegasys has seen expanded use based on its inclusion in independently developed oncology guidelines in myeloproliferative neoplasms (MPNs), PV, and ET. pharma& currently anticipates a European Commission approval decision in the coming months.

"We are delighted the European Medicines Agency's Committee for Medicinal Products for Human Use has recommended the approval of Pegasys in the EU as a treatment for all eligible patients diagnosed with polycythemia vera or essential thrombocythemia," said Frank Rotmann, Founder and Managing Director of pharma&. "Today's news is a significant milestone in pharma&'s vision to breathe new life into proven medicines and illustrates our commitment to further the development of essential medicines such as Pegasys for patients."

In response to feedback from key opinion leaders and MPN patient advocacy groups over the last few years, as well as the expanded use of Pegasys following its inclusion in independently developed oncology guidelines, pharma& submitted a label expansion to the EMA for Pegasys for the treatment of PV and ET in late 2023 to provide eligible patients with easier long-term access to the medicine they need. The positive CHMP opinion for Pegasys in PV and ET was based on 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. A product label aligned to Pegasys use in PV and ET will provide clear and concise information to help healthcare professionals and patients in the European Union understand how to use Pegasys safely and effectively.

pharma& acquired the global rights to Pegasys in 2021 from F. Hoffman La Roche AG (Roche), with the aim of ensuring continuity of care for eligible patients. Following the acquisition of Pegasys in 2021, pharma& committed to the ongoing development and future certification of the bio-manufacturing capabilities by investing in the Company's wholly-owned manufacturing plant in Austria, Loba biotech. This significant investment was required to manufacture the active pharmaceutical ingredient (API) in Pegasys, a complex biologic treatment to manufacture. The investment into Loba biotech by pharma& will ensure future access to Pegasys for eligible PV and ET patients, securing a stable supply chain long-term. This label expansion will allow pharma& to better plan and forecast product availability, ensuring that all eligible patients who reside in the EU and need Pegasys can access it across all licensed uses in the long term.

About polycythemia vera (PV) and essential thrombocythemia (ET)

Polycythemia vera (PV) and essential thrombocythemia (ET) are both myeloproliferative neoplasms (MPNs) and types of blood cancers in which the bone marrow produces blood cells that do not develop and function normally.[i,ii]

If well controlled and managed, PV and ET are both chronic, lifelong conditions.[ii,iii] PV is more common in men[iv], whereas ET is more common in women.[v] In both PV and ET, the median age of diagnoses is around 60 years of age.[iv,v]

Almost all patients diagnosed with PV have a mutation of the *JAK2* gene,[vi] and nearly 60% of ET patients also have this mutation.[vii] Its precise role in PV and ET is still being investigated.[viii]

About Pegasys® (peginterferon alfa-2a)

Pegasys is a type 1 interferon. The type I interferons present in humans are IFN-α, IFN-β, IFN-ε, IFN-κ and IFN-ω.[ix] Interferons (IFNs) and their receptors are a subset of class 2 alpha-helical cytokines that have existed in early chordates for about 500 million years and represent early elements in innate and adaptive immunity.[x] Interferons are noted

for their ability to "interfere" with viral replication within the host cells.[xi] All type I IFNs bind to a specific cell surface receptor complex, the IFN-a receptor (IFNAR), consisting of IFNAR1 and IFNAR2 chains.[xii]

Pegasys is made when interferon alfa-2a undergoes the process of pegylation in which one or more chains of polyethylene glycol, also known as PEG, are attached to another molecule.[xiii] In Pegasys, a large, branched, mobile PEG is bound to the interferon alfa-2a molecule and provides a selectively protective barrier.[xiii] The high molecular weight (40 kilodaltons) branched PEG in Pegasys has been shown to provide sustained pegylated interferon alfa-2a exposure.[xiv]

Pegasys is currently approved by the EMA for the treatment of chronic hepatitis B (CHB) in adults and children aged 3 years and older or chronic hepatitis C (CHC) in adults and children aged 5 years and older in combination with other medicinal products.[xiii]

Click here to access the current EU SmPC. For non-EU countries, please refer to your local health authority.

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

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

For medical information inquiries within the U.S., contact pharma& at medinfo.us@pharmaand.com.

You may report adverse events to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Alternatively, to report an adverse event or reaction, contact pharma& at pv@pharmaand.com.

To report a product complaint, contact pharma& at complaints@pharmaand.com.

About pharma&

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. Over the past five years, 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 development, product and API manufacturing, partner distribution, healthcare provider engagement, distribution and services to patients.

To the extent that statements contained in this press release are not descriptions of historical facts regarding pharma& they are forward-looking statements reflecting the current beliefs and expectations of management. Examples of forward-looking statements contained in this press release may include, among others, statements regarding our expectations for regulatory approvals. Such forward-looking statements involve substantial risks and uncertainties that could cause our future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. pharma& does not undertake to update or revise any forward-looking statements.

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i National Heart, Lung, and Blood Institute. Polycythemia Vera. Accessed June 18, 2024. https://www.nhlbi.nih.gov/health/polycythemia-vera

ii Essential thrombocythaemia. Blood cancer UK. Accessed June 14, 2024. https://bloodcancer.org.uk/understanding-blood-cancer/essential-thrombocythaemia-et/et-prognosis/

iii Tefferi A, et al. Polycythemia vera: historical oversights, diagnostic details, and therapeutic views. Leukemia. 2021 Dec;35(12):3339-3351. doi: 10.1038/s41375-021-01401-3.

iv Pillai AA, Fazal S, Mukkamalla SKR, et al. Polycythemia. In: StatPearls Treasure Island (FL): StatPearls Publishing; 2024 Jan

v Accurso V, et al. The Essential Thrombocythemia in 2020: What We Know and Where We Still Have to Dig Deep. Clin Med Insights Blood Disord. 2020 Dec 28;13:2634853520978210. doi: 10.1177/2634853520978210.

vi Bose P, Verstovsek S. Updates in the management of polycythemia vera and essential thrombocythemia. Ther Adv Hematol. 2019;10:2040620719870052. Published 2019 Aug 30. doi:10.1177/2040620719870052

vii Publicover A, Medd P. Myeloproliferative neoplasms. Clin Med (Lond). 2013;13(2):188-192. doi:10.7861/clinmedicine.13-2-188

viii Dos Santos LC, et al. Cytogenetics, JAK2 and MPL mutations in polycythemia vera, primary myelofibrosis and essential thrombocythemia. Rev Bras Hematol Hemoter. 2011;33(6):417-24. doi: 10.5581/1516-8484.20110116.

ix López de Padilla CM, Niewold TB. The type I interferons: Basic concepts and clinical relevance in immune-mediated inflammatory diseases. Gene. 2016 Jan 15;576(1 Pt 1):14-21. doi: 10.1016/j.gene.2015.09.058.

x Pestka S. The interferons: 50 years after their discovery, there is much more to learn. J Biol Chem. 2007 Jul 13;282(28):20047-51. doi: 10.1074/jbc.R700004200

xi Devasthanam A. S. Mechanisms underlying the inhibition of interferon signaling by viruses. Virulence. 2014; 5(2), 270–277. https://doi.org/10.4161/viru.27902

xii de Weerd, et al. Type I interferon receptors: biochemistry and biological functions. The Journal of biological chemistry. 2007; 282(28), 20053–20057. https://doi.org/10.1074/jbc.R700006200

xiii EU SmPC: European Medicines Agency. Pegasys Summary of Product Characteristics. Accessed June 18, 2024. https://www.ema.europa.eu/en/medicines/human/EPAR/pegasys#product-information-section

xiv Gao Y, et al. PEGylated therapeutics in the clinic. Bioeng Transl Med. 2023 Sep 22;9(1):e10600. doi: 10.1002/btm2.10600.