pharma& Receives FDA Approval for Pegasys® Prior Approval Supplement, Adding Loba biotech for API Production to Ensure Stable Long-term Supply in the United States

- *Loba biotech, a manufacturing site in Austria, is a wholly owned subsidiary of pharma&*
- *This approval supports long-term access to Pegasys for eligible patients who depend on this critical therapy*

Intended for the Healthcare Media

Vienna, Austria, August 19, 2026 – pharmaand GmbH (pharma&) today announced that the U.S. Food and Drug Administration (FDA) has approved a Prior Approval Supplement (PAS) for Pegasys® (peginterferon alfa-2a), for the registration of Loba biotech GmbH, a wholly owned manufacturing subsidiary of pharma&, to produce the active pharmaceutical ingredient (API) peginterferon alfa-2a. This approval reinforces the long-term stability of the U.S. supply, ensuring continuity of care for eligible patients.

"We are delighted that the FDA has granted PAS approval so peginterferon alfa-2a can be produced at Loba biotech GmbH – this follows approvals from other regulatory agencies across the globe," said Elmar Zagler, Co-Founder and Managing Director, pharma&. "Since acquiring peginterferon alfa-2a in 2021, pharma& has committed to maintaining access to the medicine for eligible patients, and this approval marks a significant step in supporting continuous supply in the U.S. and underscores our ongoing commitment to patients."

In 2019, F. Hoffmann La Roche AG (Roche) announced that it would cease commercializing peginterferon alfa-2a globally. pharma& acquired the global rights to peginterferon alfa-2a in 2021 from Roche, intending to ensure continuity of care for eligible patients. Following its acquisition, pharma& encountered a surge in product demand. As a result of the growing need among eligible patients, pharma& committed to investing in bio-manufacturing capabilities at pharma&'s wholly owned manufacturing site subsidiary, Loba biotech GmbH. The company also promptly implemented mitigation strategies designed to optimize availability alongside proactively working with the FDA to limit any potential interruptions in availability in the U.S. This significant investment was essential to enable the new site to produce the API peginterferon alfa-2a, and without pharma&'s investment, future availability would not have been possible.

Replenishing peginterferon alfa-2a worldwide remains a top priority, and pharma&, alongside its partners, is actively collaborating with regulatory authorities to enhance availability for eligible patients globally. To date, pharma& has obtained a drug substance manufacturing site change to Loba biotech for peginterferon alfa-2a API production across the European Union, United Kingdom, Switzerland, Kosovo, Singapore, United Arab Emirates, Hong Kong, Albania, Australia and Canada. Further approvals are under review in numerous countries and are pending.

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About Pegasys® (peginterferon alfa-2a)

Peginterferon alfa-2a is a type I interferon. The type I interferons present in humans are IFN-α, IFN-β, IFN-ε, IFN-κ, and IFN-ω.[i] [i] 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.[ii] IFNs are noted for their ability to "interfere" with viral replication within the host cells.[iii] All type I IFNs bind to a specific cell surface receptor complex, the IFN-α receptor (IFNAR), consisting of IFNAR1 and IFNAR2 chains.[iv]

Peginterferon alfa-2a is made when interferon alfa-2a undergoes the process of pegylation, in which one or more chains of polyethylene glycol (PEG) are attached to another molecule.[v, vi] In Pegasys, a large, branched, mobile PEG is bound to the interferon alfa-2a molecule and provides a selectively protective barrier.[v, vi] To prolong the pharmacokinetic, the high molecular weight (40 kilodaltons) branched PEG is covalently bound to IFN alfa 2a to exert in peginterferon alfa-2a.[vii]

peginterferon alfa-2a United States full package insert (USPI), including authorized use and complete safety information.

peginterferon alfa-2a is approved by the FDA for the treatment of chronic hepatitis B (CHB) in adults and non-cirrhotic children aged 3 years and older, and for the treatment of chronic hepatitis C (CHC) in adults (in combination with other medicinal products) and in children aged 5 years and older (in combination with ribavirin).[v]

For a full list of adverse events, information on dosage and administration and other precautions when using peginterferon alfa-2a, please refer to the current USPI here.

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.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.

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