pharma& Receives EMA Approval for Pegasys® Manufacturing Site Variation, Adding Loba biotech for API Production and Securing a Stable, Long-term Supply

- *Loba biotech, a manufacturing site in Austria, is a wholly owned subsidiary of pharma&*
- *With this approval, the replenishment of Pegasys across Europe begins, restoring access for eligible patients who rely on this essential treatment*

Intended for the Healthcare Media

Vienna, Austria, April 29, 2025 – pharmaand GmbH (pharma&) today announced that the European Medicines Agency (EMA) has granted a variation to the Marketing Authorization for Pegasys® (peginterferon alfa-2a), allowing Loba biotech GmbH, a wholly owned manufacturing subsidiary of pharma&, to be included as an approved site for the production of the active pharmaceutical ingredient (API), peginterferon alfa-2a. The approval enables pharma& to begin Pegasys product replenishment across Europe and bolsters enduring supply chain resilience. pharma& anticipates eligible European patients should start to experience improved Pegasys availability in the coming weeks.

"We are thrilled to announce the EMA's approval for Pegasys API production at Loba biotech GmbH. This is a key milestone on the path to Pegasys replenishment across Europe today and in other regions in the near future," said Elmar Zagler, Founder and Managing Director, pharma&. "Since acquiring Pegasys, pharma& has been committed to ensuring this important medicine's continuous availability to eligible patients. Our investment in Loba biotech and the EMA's approval is a pivotal step in delivering on pharma&'s mission to preserve the availability and foster the further development of essential medicines worldwide to leave no patient behind."

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, intending to ensure continuity of care for eligible patients. Following pharma&'s acquisition of Pegasys, pharma& encountered increased 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 plant subsidiary, Loba biotech GmbH. This significant investment was essential for the new plant to produce the API in Pegasys.

Replenishing Pegasys outside of Europe is a top priority, and pharma&, alongside its partners, is actively collaborating with regulatory authorities to enhance availability for eligible patients in the U.S. and other regions as swiftly as possible.

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About Pegasys® (alfa-2a)

Pegasys 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] 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]

Pegasys 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 In Pegasys, a large, branched, mobile PEG is bound to the interferon alfa-2a molecule and provides a selectively protective barrier.[v] prolonged the pharmacokinetic the high molecular weight (40 kilodaltons) branched PEG is covalently bound to IFN alfa 2a to exert in Pegasys.[vi]

Pegasys® (peginterferon alfa-2a) European Union (EU) Member States, Iceland, Norway, authorized use and access to the full SmPC, including complete safety information.

In August 2024, the European Commission (EC) approved Pegasys as monotherapy in adults for the treatment of polycythaemia vera (PV) and in adults for the treatment of essential thrombocythemia (ET).[v]

The EC previously approved Pegasys 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 in adults or ribavirin in children.[v]

For a full list of adverse events and information on dosage and administration and other precautions when using Pegasys, please refer to the EU Summary of Product Characteristics, click here. 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.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. 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 active pharmaceutical ingredients (API) manufacturing, partner distribution, healthcare provider engagement, distribution and services to patients.

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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