MHRA approves pharmaand GmbH's Pegasys® (peginterferon alfa-2a) as a treatment for eligible patients with the myeloproliferative neoplasms (MPNs) blood cancers polycythemia vera (PV) and essential thrombocythemia (ET)

- First MHRA approval of an interferon alfa as a monotherapy treatment for adults with essential thrombocythemia (ET)
- First MHRA approval of an interferon alfa as a monotherapy treatment for adults with polycythemia vera (PV) without any restrictions

Intended for the Healthcare Media

Vienna, Austria, July 16, 2025 – pharmaand GmbH (pharma&) announced today that the Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for Pegasys® (peginterferon alfa-2a) as a monotherapy treatment for adults with polycythemia vera (PV) or essential thrombocythemia (ET). PV and ET are both myeloproliferative neoplasms (MPNs), types of rare blood cancers in which the bone marrow produces peripheral blood cells that do not develop and function normally.[i, ii]

"With this approval we will now have the opportunity to reach additional eligible patients in the United Kingdom in need of treatment options for two chronic, rare blood cancers, polycythemia vera, and essential thrombocythemia," said Frank Rotmann, Founder and Managing Director of pharma&. "This regulatory milestone aligns with pharma&'s mission to preserve the availability and foster the further development of essential medicines worldwide to leave no patient behind."

The MHRA based its approval 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 in 2022 and 2019, respectively.

"While peginterferon alfa-2a has been recommended for use in hematology guidelines for the treatment of polycythemia vera and essential thrombocythemia, today's MHRA approval provides clear and concise information on the place," said Dr. Claire Harrison

MD, Professor of Myeloproliferative Neoplasms (MPN) at the Guy's and St. Thomas' NHS Foundation Trust in the United Kingdom. "People living with these two chronic types of blood cancer need and deserve additional treatment options, and today's approval is positive news for eligible patients in the United Kingdom."

"This approval marks a hopeful moment for the MPN community in the UK. We at MPN Voice (www.MPNVoice.org.uk) are deeply encouraged to see patient needs being recognized and prioritized," said Mrs. Nona Baker co-chair MPN Voice. "This is a significant step forward to ensure all eligible patients with polycythemia vera or essential thrombocythemia have access to therapy options they deserve."

Following the acquisition of peginterferon alfa-2a in 2021 from F. Hoffmann La Roche AG (Roche), pharma& committed to the ongoing development and the certification of the bio-manufacturing capabilities by investing in the Company's wholly-owned manufacturing plant in Austria, Loba biotech GmbH. On May 22, 2025, pharma& received MHRA approval for the peginterferon alfa-2a manufacturing site variation. Coupled with the manufacturing site variation, this label expansion will allow pharma& to better plan and forecast product availability, ensuring that all eligible patients in the United Kingdom can access peginterferon alfa-2a in the long term.

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About 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.[iii] 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.[iv] IFNs are noted for their ability to "interfere" with viral replication within the host cells.[v] All type I IFNs bind to a specific cell surface receptor complex, the IFN-α receptor (IFNAR), consisting of IFNAR1 and IFNAR2 chains.[vi]

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.[vii,viii] In peginterferon alfa-2a, a large, branched, mobile PEG is bound to the interferon alfa-2a molecule and provides a selectively protective barrier.[vii,viii] 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.[ix]

Peginterferon alfa-2a Medicines and Healthcare products Regulatory Agency (MHRA) authorized use and access to the full SmPC, including complete safety information.

In the UK, peginterferon alfa-2a is indicated as monotherapy in adults for the treatment of polycythemia vera and as monotherapy in adults for the treatment of essential thrombocythemia.

Peginterferon alfa-2a was previously approved 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.[viii]

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

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.

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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