FOR IMMEDIATE RELEASE

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Global Regulatory Partners Announces MHLW Approval of Pegfilgrastim Biosimilar in Japan

Approval marks GRP GK's second biosimilar approval in Japan and strengthens its collaboration with Biocon Biologics and Sandoz

Tokyo, Japan – August 25, 2026 – **Global Regulatory Partners GK (GRP GK)** announced today that Japan's Ministry of Health, Labour and Welfare (MHLW) **granted marketing approval on August 24, 2026,** for **Pegfilgrastim BS Subcutaneous Injection 3.6 mg 「GRP」,** a pegfilgrastim biosimilar indicated for the prevention of febrile neutropenia associated with cancer chemotherapy.

Pegfilgrastim BS Subcutaneous Injection 3.6 mg 「GRP」 is a long-acting granulocyte colony-stimulating factor (G-CSF) administered once per chemotherapy cycle. The approval expands the availability of biosimilar treatment options in Japan for the prevention of febrile neutropenia associated with cancer chemotherapy and represents an important milestone in the collaboration between **Global Regulatory Partners GK, Biocon Biologics Ltd., and Sandoz K.K.** to bring high-quality biosimilar medicines to patients in Japan.

The approval also marks **GRP GK's second biosimilar approval in Japan**, further demonstrating the company's growing experience as an independent Marketing Authorization Holder supporting global biopharmaceutical companies in bringing biosimilar medicines to the Japanese market.

Dr. Suzan Davis, Chief Executive Officer, Global Regulatory Partners GK, said:

"We are proud to have supported Biocon and Sandoz in achieving this important milestone for patients in Japan. This approval reflects the strength of our collaboration and GRP's commitment to expanding patient access to affordable, high-quality biologic medicines. As Marketing Authorization Holder, we remain committed to ensuring the highest standards of quality, safety, and compliance throughout the product lifecycle."

Yohei Ishii, Country Head, Sandoz Japan, said:

"We are delighted to further strengthen our biosimilar portfolio and expand access to high-quality, affordable biologic medicines for patients across Japan. This latest approval represents another important milestone in broadening treatment options for patients in Japan, while supporting the long-term sustainability of Japan's healthcare system through safe, effective and high-quality biosimilars."

Matt Erick, Chief Commercial Officer, Advanced Markets, Biocon, said:

"The approval of our pegfilgrastim biosimilar in Japan reflects Biocon's continued commitment to broadening access to affordable, high-quality biologic medicines globally. We are proud to engage with Sandoz as our promotion, distribution and sales partner, and with GRP as our Marketing Authorization Holder and regulatory partner in Japan, and we will collaboratively meet the needs of patients and healthcare professionals in Japan."

About Pegfilgrastim BS

Pegfilgrastim BS Subcutaneous Injection 3.6 mg 「GRP」 is a long-acting granulocyte colony-stimulating factor (G-CSF) indicated for the **prevention of febrile neutropenia associated with cancer chemotherapy**. The approved dosage is **3.6 mg administered by subcutaneous injection once per chemotherapy cycle, beginning the day after completion of chemotherapy**. The product is supplied as a single-use prefilled syringe containing 3.6 mg of pegfilgrastim in 0.36 mL.

The product was developed and is manufactured by **Biocon Biologics Ltd.**, is registered in Japan by **Global Regulatory Partners GK as the Marketing Authorization Holder (MAH)**, and will be promoted and commercialized by **Sandoz K.K.**

Notes to Editors

About Global Regulatory Partners GK

Global Regulatory Partners GK (GRP GK) is the Japanese affiliate of Global Regulatory Partners, Inc. (GRP Inc.) and a licensed **Marketing Authorization Holder (MAH)** headquartered in Tokyo, Japan. Operating in Japan since 2016, GRP GK provides **integrated services and local representation** to international pharmaceutical, biotechnology, and healthcare companies seeking to register, launch, commercialize, and maintain products in Japan.

GRP's mission is to **accelerate access to innovative healthcare products and technologies for patients in Japan**. Through its local expertise and international network, GRP serves as a bridge between global healthcare innovation and patients and healthcare providers in Japan, helping international companies navigate the regulatory and operational requirements necessary to bring their products to the Japanese market.

GRP GK has established a growing track record supporting **specialty, orphan, biologic, and biosimilar medicines**. In July 2024, GRP GK served as the Japanese MAH for the approval of **Aflibercept BS Solution for Intravitreal Injection 40 mg/mL [GRP]**, in collaboration with foreign manufacturer **Samsung Bioepis**. This was followed in August 2026 by the approval of **Pegfilgrastim BS Subcutaneous Injection 3.6 mg 「GRP」** in collaboration with **Biocon Biologics Ltd. and Sandoz K.K.**, marking GRP GK's **second biosimilar approval in Japan**. GRP GK also serves as the Japanese MAH for **Baqsimi® (nasal glucagon)**, following the transfer of the Marketing Authorization from **Eli Lilly Japan to GRP GK on behalf of Amphastar Pharmaceuticals in 2025**.

Together, these milestones reflect GRP GK's expanding role in the Japanese healthcare industry and its commitment to accelerating patient access to important healthcare innovations in Japan.

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