ACCORD HEALTHCARE'S (INTAS) PELGRAZ® (PEGFILGRASTIM) GIVEN GREEN LIGHT BY CHMP

Pelgraz - a pegylated G-CSF Biosimilar, is latest addition to Accord Healthcare's established portfolio of over 30 oncology treatments across Europe. Following marketing authorisation Accord Healthcare will potentially be the first to launch pegfilgrastim across Europe

The Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Accord's Pelgraz (pegfilgrastim), pegylated granulocyte-colony stimulating factor (G-CSF) biosimilar in Europe. Once approved, Pelgraz could be the first pegfilgrastim biosimilar to market in Europe indicated to reduce the duration of neutropenia and the incidence of febrile neutropenia for adult patients undergoing cytotoxic chemotherapy. The World Health Organisation consider G-CSF essential therapies due to their impact on febrile neutropenia, chemotherapy dose delays, and dose density.

Neutropenia is still one of the most common reasons for reductions or delays in the chemotherapy schedule which impairs survival outcomes and quality of life for patients. Evidence shows that daily G-CSFS are incorrectly administered in 42% of chemotherapy cycles, long acting pegfilgrastim has been shown to greatly reduce that figure to just 8%.

Dr Cornes, Consultant Oncologist, Bristol, "Pegfilgrastim is a wonderful medicine. It enables cancer chemotherapy to be given on time and at the right dose - giving patients the greatest chance of an uncomplicated cure. As a single injection for each cycle of chemotherapy it offers advantages in dosing and compliance over first generation short-acting filgrastim - which results in real world improvements for patients."

Binish Chudgar, Vice Chairman and Managing Director of the Intas Group "Accord launched its first European approved biosimilar product, Accofil (filgrastim), in 2015 and despite being the 6th entrant has become a leading supplier of this vital medicine. Since then the product has been used over 2 million times and Accord has gained valuable experience in bringing biosimilar medicines to market. Our continued focus on bringing biopharmaceuticals to Europe has enabled us to be a first to launch a pegfilgrastim, and as a first mover we expect to gain an even bigger market share with Pelgraz."

Intas / Accord will manufacture Pelgraz in its own state of the art production facility. The company has deep experience with biosimilar medicines and as of 2017 were assessed as having the second highest number of biosimilars in phase III to approval in the world. This reflects the strategy of a long-standing commitment in biopharmaceutical development, research and manufacturing.

The CHMP positive opinion was based on Pelgraz's substantial clinical development programme, which supported its biosimilarity with Neulasta® through a Phase I, randomised, assessor-blinded PK/PD study in healthy volunteers, and a Phase III study of patients with breast cancer (stage IIa, IIb, or IIIa) on TAC (docetaxel, doxorubicin, cyclophosphamide).

Paul Tredwell, Accord VP Speciality Brands, EMENA "At Accord, our mandate is to deliver affordable medicines that make a real difference to patient's lives. With Pelgraz approval and commercialisation, we hope to provide patients with the first pegylated biosimilar of pegfilgrastim that will reduce the

strain on healthcare providers budget, while potentially improving standard of care and associated outcomes for patients."

Tredwell concluded "Accord is providing affordable alternatives in some of the most complex areas of medicine and Pelgraz is the latest medicine reflecting our increased focus in speciality pharmaceuticals (including oncology, critical care, auto-immune, fertility and central nervous system conditions.) We already have an established footprint across Europe, directly serving 93% of the European population with over 30 oncology therapies via our own commercial infrastructure, and this latest recommendation further underlines our commitment to oncology patients."