# News Release

## Accord Healthcare's Pelgraz® Approved by EMA

***For the first time in Europe, a pegylated G-CSF biosimilar pegfilgrastim will be available to patients for the treatment of neutropenia***

***Accord Healthcare first to launch pegfilgrastim across Europe***

The European Medicines Agency (EMA) has approved Accord's Pelgraz (pegfilgrastim), pegylated granulocyte-colony stimulating factor (G-CSF) biosimilar in Europe. The first countries will launch immediately on receipt of their Marketing Authorisation and appropriate national price & reimbursement activities, which we anticipate will make Accord the first to market a biosimilar pegfilgrastim in Europe. Pelgraz is indicated to reduce the duration of neutropenia and the incidence of febrile neutropenia for adult patients undergoing cytotoxic chemotherapy.[1]

Professor Matti Aapro, Board Director, Genolier Cancer Centre, Switzerland, "Neutropenia is still one of the most common reasons for reductions or delays in the chemotherapy schedule, which can significantly decrease survival outcomes and quality of life for patients. Evidence shows that daily G-CSFS are incorrectly administered in 42% of chemotherapy cycles, whereas, long acting pegfilgrastim has been shown to greatly reduce that figure to just 8%."

The approval was based on the clinical development programme for Pelgraz, which supported its biosimilarity with Neulasta®. Pelgraz is the only approved biosimilar treatment in the EU that has phase III clinical data in addition to phase I as part of its efficacy and safety profile.[2,3]

Dr Paul Cornes, Consultant Oncologist, Bristol, "This is an important development for the thousands of cancer patients in Europe undergoing chemotherapy who will have greater access to this vital medicine in their cancer treatment journey. Patients want to spend less time in hospitals and have more time to enjoy life. Pegfilgrastim is one dose per cycle administration, which may reduce the need for white blood cell count monitoring and patients avoid the potential worry of daily injections.[4]

Paul Tredwell, Accord VP Speciality Brands, EMENA "This approval builds on our established expertise and extensive oncology treatment portfolio. We are committed to ensuring that Pelgraz will be made available as each country concludes its regulatory process. We anticipate being first out of production and into the healthcare professional's hands in most European markets."

Pelgraz® is the latest addition to Accord's established portfolio of over 30 oncology treatments across Europe.[5] Accord will manufacture Pelgraz in its own state of the art production facility. Accord joins a very limited number of companies who have developed, manufactured and launched a first to market biosimilar.

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.[6] This reflects the strategy of a long-standing commitment in biopharmaceutical development, research and manufacturing.

***ends***

**Notes to editors**

- Spokespersons are available for further comment

**Media Enquiries**

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**About Accord Healthcare**

Headquartered in the United Kingdom (UK), Accord Healthcare Europe is the fastest growing generic pharmaceutical companies in Europe. Accord has an extensive supply chain through its four UK based sites, helping to ensure a consistent supply of life-enhancing medicines for patients, whilst supporting customers to react quickly to dynamic market conditions.

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[1] Neulasta (pegfilgrastim) Summary of Product Characteristics (SmPC)
[2] Singh I, Patel A, Patel R, Jose V. Pharmacokinetic and pharmacodynamic bioequivalence study of a pegfilgrastim biosimilar INTP5 in healthy subjects. *Cancer Chemother Pharmacol*. 2018 Aug;82(2) 329-337. doi:10.1007/s00280-018-3620-x. PMID: 29948023
[3] Desai, K., Catalano, T., Rai, G., Misra, P., Shah, N. Confirmation of biosimilarity in a Pharmacokinetic/Pharmacodynamic study in healthy volunteers for an analytically highly similar pegfilgrastim. Clin Pharmacol Drug Dev. 2016;5:354–363
[4] Holmes FA et al *Annals of Oncology*, Volume 13, Issue 6, 1 June 2002, Pages 903–909, https://doi.org/10.1093/annonc/mdf130
[5] Accord data on file
[6] IQVIA MIDAS MAT Q3 2017; IQVIA Institute Jan 2018