Mundipharma launches Pelmeg®▼(pegfilgrastim) biosimilar in Europe

- *Germany, the Netherlands and Ireland are the first markets to launch Pelmeg®.*
- *Pelmeg, a pegfilgrastim biosimilar, is indicated for the reduction of the duration of neutropenia and incidence of febrile neutropenia in adults treated with chemotherapy.*[1]
- *Developed by Cinfa Biotech, part of the Mundipharma network of independent associated companies, Pelmeg becomes the fourth biosimilar in Mundipharma's portfolio, building on Mundipharma's proven commercial excellence and further expanding its commercial footprint, with further launches expected across Europe subject to local approval processes.*

CAMBRIDGE, UK: 05 February 2018 – The Mundipharma network of independent associated companies today announced the launch of Pelmeg® (pegfilgrastim), a biosimilar of Neulasta® following European Commission (EC) approval in November 2018.[2] Pelmeg is the fourth biosimilar medicine to be commercialised by Mundipharma, expanding its portfolio and commercial footprint across Europe. It was developed by Cinfa Biotech which was acquired by Mundipharma and announced in October 2018.

Now available in Germany, the Netherlands and Ireland, Pelmeg is indicated for the reduction of the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).[1]

"We are delighted that Pelmeg is now available in these countries. The launch of the treatment builds on our proven commercial excellence in biosimilars over the past four years. Pelmeg has the potential to play an important role in improving the lives of patients affected by chemotherapy induced neutropenia and febrile neutropenia," said Philippe Bastide, Head of Biosimilars, Europe. "Through our partnership with Celltrion, we estimate Remsima® and Truxima® have already saved European healthcare systems approximately €330m.[3*] If all patients currently being treated with the reference product are offered access to Pelmeg, further significant savings can be realised for the healthcare community."

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The acquisition of Cinfa Biotech provides Mundipharma with global reach and expanded development capabilities. Mundipharma will continue to leverage partnerships to develop its expanding portfolio of Biosimilars, reinforcing its leadership in Europe and extending its geographical footprint.

-Ends-

▼ This medicinal product is subject to additional monitoring.

*Figures relate to data from 2015-2017

Notes to editors

About the clinical data

A comprehensive analytical, biofunctional, preclinical and clinical comparability programme has demonstrated a high degree of similarity between Pelmeg and Neulasta®.[4] Its biosimilarity has been studied in healthy volunteers who have no comorbidities, require no co-medication and are immunocompetent.[5,6,7]

The data:

- Confirmed biosimilarity to Neulasta in sensitive clinical study settings
- Demonstrated pharmacokinetic comparability to Neulasta at the clinical dose of 6 mg
- Demonstrated pharmacodynamic comparability to Neulasta at the clinical dose of 6 mg and at the reduced dose of 3 mg
- Did not show any clinically meaningful differences in the safety and immunogenicity profile compared to Neulasta

About Pelmeg

It is a pegfilgrastim biosimilar.[1] Pegfilgrastim is a pegylated version of granulocyte-colony stimulating factor (G-CSF) that works by stimulating the bone marrow to produce more neutrophils, thereby reducing the duration of neutropenia and the incidence of febrile neutropenia. It is administered as a subcutaneous injection once per chemotherapy cycle, at least 24 hours after cytotoxic chemotherapy.[1]

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The approval of Pelmeg was based on a robust regulatory submission of rigorous analytical, biofunctional, preclinical and clinical studies to demonstrate biosimilarity in terms of its quality, safety and efficacy profile compared with the reference pegfilgrastim.[4] As such, it is indicated in the exact same way as subcutaneous (pre-filled syringe) Neulasta.

Most standard-dose chemotherapy regimens are associated with 6–8 days of neutropenia, and febrile neutropenia is observed in approximately 8 cases per 1000 patients receiving cancer chemotherapy. People with febrile neutropenia caused by chemotherapy treatment for cancer are at increased risk of severe infection and death.[8]

About neutropenia and febrile neutropenia

People taking chemotherapy for cancer are at risk of dangerously low levels of a type of white blood cell called a neutrophil. Neutrophils play an important role in the immune system guarding against infection. Febrile neutropenia is a low level of neutrophils in the blood accompanied by a fever.[9]

About the Mundipharma network

The Mundipharma network of independent associated companies has distribution and marketing rights from Celltrion Healthcare for three prior biosimilars – Remsima®, Truxima® and Herzuma® – in Germany, Luxembourg, Ireland (Truxima® and Herzuma® only), Italy, UK, Netherlands and Belgium.

The Mundipharma global network of privately-owned independent associated companies was founded in 1956 by doctors and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

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[2] European Medicines Agency. Pelmeg® (pegfilgrastim) European Public Assessment Report. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/pelmeg#overview-section. Last accessed January 2019

[3] Figures based on Mundipharma data – Biosimilar savings: truxima and remsima net price vs originator list price x units or vials sold. Time periods are from launch, with data based on five markets for Remsima and six markets for truxima through to year end 2017

[4] European Medicines Agency. Pelmeg® (pegfilgrastim) European Public Assessment Report. Available at: https://www.ema.europa.eu/documents/assessment-report/pelmeg-epar-public-assessment-report_en.pdf. Last accessed January 2019

[5] Roth K et al. Demonstration of pharmacokinetic and pharmacodynamic comparability in healthy volunteers for B12019, a proposed pegfilgrastim biosimilar. Abstract 241. Presented at the European Cancer Congress (ECCO), 27–30 January 2017, Amsterdam, The Netherlands.

[6] Roth K et al. Comparability of pharmacodynamics and immunogenicity of B12019, a proposed pegfilgrastim biosimilar to Neulasta®. Abstract 1002. Presented at the 59th American Society of Hematology (ASH) Annual Meeting, 9–12 December 2017, Atlanta, USA.

[7] Roth K et al. Pharmacokinetic and pharmacodynamic comparability of B12019, a proposed pegfilgrastim biosimilar. Poster 1573. Presented at the European Society for Medical Oncology (ESMO), 8–12 September 2017, Madrid, Spain.

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