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European Commission approves *Pelmeg*▼® (pegfilgrastim) as a biosimilar treatment to reduce the duration of neutropenia and incidence of febrile neutropenia in adults treated with chemotherapy

- Pelmeg is a pegfilgrastim biosimilar that is delivered subcutaneously to reduce 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]
- Pelmeg has been through rigorous analytical, biofunctional, preclinical and clinical studies to demonstrate biosimilarity in terms of its quality, safety and efficacy profile compared with the reference pegfilgrastim[2]
- Pelmeg was developed by Cinfa Biotech, now part of the Mundipharma network of independent associated companies.

CAMBRIDGE, UK: 23 November 2018 - The Mundipharma network of independent associated companies today announced that the European Commission (EC) has granted approval for the use of Pelmeg® (pegfilgrastim) as a treatment for reduction in 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]

The EC's decision follows a recommendation from the Committee for Medicinal Products for Human Use (CHMP) that was based on a robust regulatory submission of key biosimilarity data from analytical, biofunctional and clinical study comparisons for Pelmeg.[2] In all cases it demonstrated comparable pharmacodynamics, pharmacokinetics, and immunogenicity to its reference product Neulasta.[3,4,5] The information submitted, and conclusions reached, were comprehensive enough to extrapolate the indication for Neulasta across to Pelmeg.[2] As such, it is indicated in the exact same way as subcutaneous (pre-filled syringe) Neulasta.

"We hope this approval will significantly improve the lives of people who are affected by chemotherapy induced neutropenia and febrile neutropenia. The availability of this biosimilar represents an important opportunity to reduce healthcare costs while increasing access to an effective treatment option," said Philippe Bastide, Head of Biosimilars, Mundipharma International.

Pelmeg is the fourth biosimilar medicine to be commercialised by the Mundipharma network. It was developed by Cinfa Biotech which was acquired by the Mundipharma network and announced in October 2018. The acquisition of Cinfa Biotech provides Mundipharma with global reach and expanded development capabilities.

#ENDS#

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▼ This medicinal product is subject to additional monitoring.

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. Its biosimilarity has been studied in healthy volunteers who have no comorbidities, require no co-medication and are immunocompetent.[3,4,5]

The Pelmeg 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®

Pelmeg is a pegfilgrastim biosimilar.[6] 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 incidence of febrile neutropenia. It is administered as a subcutaneous injection once per chemotherapy cycle, at least 24 hours after cytotoxic chemotherapy.[6]

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.[7]

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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Pelmeg® is a registered trademark of Cinfa Biotech, S.L.

Herzuma®, Truxima® and Remsima® are all registered trademarks of Celltrion Inc. and are used under license.

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