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ASIA EDITION

Teva's Lonquex gets EU market authorization

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Singapore:Ã?Â European Medical Association's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended that a marketing authorization may be issued in the European Union for Teva Pharmaceutical's Lonquex (XM22 lipegfilgrastim).

The drug is indicated 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 leukemia and myelodysplastic syndromes). CHMP opinion paves the way to a final approval decision from the European Commission expected within the next few months.

Lonquex (lipegfilgrastim) is a long-acting recombinant granulocyte colony-stimulating factor (G-CSF) based on novel GlycoPEGylation technology. Lipegfilgrastim is a novel, pegylated and glycosylated long-acting form of filgrastim, intended for once-per-cycle fixed dose, subcutaneous injection for neutrophil support in patients receiving myelosuppressive chemotherapy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes).

Dr Michael Hayden, Teva's president of global R&D and CSO, commented, "Effective prophylaxis against neutropenia and febrile neutropenia is a high priority for patients undergoing cytotoxic chemotherapy. This chemotherapy attacks rapidly dividing bone marrow cells and dramatically reduces the ability to fight off infection, which can have serious consequences for patients. Loquenex reduces the neutropenia that can lead to these consequences. We look forward to receiving final approval and being able to offer this medication to patients."

"The CHMP positive opinion is an important milestone in Teva's efforts to provide new treatment options for patients in oncology, which is a key area of focus for Teva," stated Dr Rob Koremans, president and CEO, Teva Global Specialty Medicines. "We will now await the final decision from the European Commission. Teva is highly committed in delivering innovative treatments to market and its stakeholders that meet patients' needs."