

Press release

Biosimilar Ratiograstim[®] receives EMEA approval

First biosimilar for the treatment of neutropenia

Ulm, September 2008. ratiopharm has received approval for the first filgrastim biosimilar from the EU regulatory office, EMEA. The market launch of Ratiograstim[®] will take place in the fourth quarter of 2008. "This first biosimilar to be launched on the market by the ratiopharm Group is backed by 125 years of experience in research and development and underscores ratiopharm's position as an innovative generics company," said ratiopharm Group CEO Oliver Windholz.

Ratiograstim[®]'s active ingredient is filgrastim, a so-called granulocyte colony-stimulating factor (G-CSF), which is approved for the treatment of certain types of neutropenia and to mobilize stem cells. Filgrastim counteracts the depletion of white blood cells during chemotherapy, especially in cancer patients, and prevents potentially fatal infections in patients with this condition.

Innovative therapies at affordable prices

Due to the high costs of development and production, biopharmaceuticals are among the most expensive medications on the market. The market launch of biosimilars, such as Ratiograstim[®], now potentially makes these types of innovative therapies accessible to a much larger group of patients. Despite the cost-intensive and time- and energy-consuming development and production flows, ratiopharm is offering

Ratiograstim[®] at an affordable price. This means that ratiopharm is making an effort to lower healthcare costs.

Large-scale study programme

The approval for biosimilars is subject to high standards with stringent criteria stipulated by the EMEA. For the approval of Ratiograstim[®], large-scale Phase I and III clinical trials were carried out involving around 880 subjects and patients. In these time-consuming clinical trials it was proven that Ratiograstim[®] offers a quality, safety and efficacy profile comparable to the reference product, Neupogen[®]. This comparable high quality was proven as part of the approval dossier.

The comprehensive and cost-intensive pre-clinical and clinical development for Ratiograstim[®] was managed and implemented by BioGeneriX, a subsidiary of ratiopharm.

Data from the approval trials

The standards for trials with biosimilars are comparable to those for the original biopharmaceutical. For Ratiograstim[®] the clinical studies were carried out in patients with breast cancer (stages II to IV), lung cancer and non-Hodgkin's lymphoma who were undergoing chemotherapy with cytostatics. In the multi-centre Phase II trials, Ratiograstim[®] proved to be comparable to the reference product in terms of efficacy and safety. The endpoints were the reduction in the duration of severe neutropenia and in the incidence of febrile neutropenia.

One of the major aspects in assessing the safety of biopharmaceuticals is the question of immunogenicity, because all biotechnologically produced proteins can basically trigger an immune response. In the antibody tests carried out for Ratiograstim[®] it was demonstrated that

the ratiopharm biosimilar has a comparable immunogenicity profile to the reference product.

ratiopharm biosimilars – A mainstay for the future

The first approval for a ratiopharm biosimilar after nearly 10 years of research work in this area marks the first success of the ratiopharm Group's biopharmaceutical activities. Other products from the biotech drug portfolio will follow. Ratiograstim® will be sold on the European pharmaceutical market by the ratiopharm direct subsidiary and by ratiopharm International.

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