Press Release
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CHMP issues positive opinion on Type II variation to extend the therapeutic indication of Pepaxti based on OCEAN trial results

Stockholm — September 14, 2023 — Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces that the Committee for Medicinal Products for Human Use (CHMP), part of the European Medicines Agency (EMA), has, following their scientific assessment, adopted a positive opinion on Oncopeptides' application for earlier lines of treatment for patients with relapsed, refractory multiple myeloma (RRMM). The opinion from the CHMP will now be sent to the European Commission for a final decision.

Based on findings from its OCEAN trial, Oncopeptides submitted, on 28 Nov 2022, an application to extend the therapeutic indication of Pepaxti to the treatment of adult patients with multiple myeloma who have received at least two prior lines of therapies, whose disease is refractory to lenalidomide and the last line of therapy.

With their opinion, CHMP recommends that the use of Pepaxti could be expanded to earlier lines of treatment and also peripheral administration, meaning delivery of treatment through peripheral rather than central veins, a less invasive way of administration.

Oncopeptides will as a next step assess the current market dynamics of the rapidly evolving multiple myeloma landscape, including the competition in different lines of treatment and the effect that extending Pepaxti into earlier lines of treatment would have on Oncopeptides ´ ability to receive a reimbursed price that reflects its innovation.

"The positive opinion from the CHMP further validates the scientific data on the efficacy, safety and increased quality of life that Pepaxti is able to bring to patients," says Sofia Heigis, CEO of Oncopeptides. "While we are convinced that our drug best serves patients in later lines of treatment where the unmet need and our chances to receive a price that reflects our innovation are high, we will closely evaluate the CHMP opinion and our potential next steps, always keeping value for patients and our shareholders as paramount priorities."

For more information, including a Q&A for investors, please visit Oncopeptides' web site.

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This information is information that Oncopeptides is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-09-14 15: 50 CEST.

About Oncopeptides

Oncopeptides is a biotech company focused on research, development, and commercialization of therapies for difficult-to-treat hematological diseases. The company uses its proprietary Peptide Drug Candidate platform (PDC) to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells.

Pepaxti® (melphalan flufenamide, also called melflufen) has been granted Marketing Authorization, in the European Union, the EEA-countries Iceland, Lichtenstein and Norway, as well as in the UK. Pepaxti is indicated in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapies, whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation. Melflufen has been granted accelerated approval in the US under the trade name Pepaxto®. The drug is currently not marketed in the US.

Oncopeptides is developing several new compounds based on its proprietary technology platforms and is listed on the Small Cap segment on Nasdaq Stockholm with the ticker ONCO. For more information see: www.oncopeptides.com.

Attachments

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