Press Release
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CHMP issues positive opinion of label expansion of Pepaxti to third-line treatment

STOCKHOLM — September 17, 2026 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on difficult-to-treat cancers, today announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending an extension of the therapeutic indication for Pepaxti (melflufen) to earlier lines of therapy. The positive opinion will now be referred to the European Commission (EC) for a final decision.

Under the adopted opinion, the CHMP recommends expanding the therapeutic indication of Pepaxti, in combination with dexamethasone, to adult patients with multiple myeloma who have received at least two prior lines of therapies (third line and later), and whose disease is refractory to lenalidomide and the last line of therapy.

Currently, Pepaxti is approved in the European Union for adult patients who have received at least three prior lines of therapy and are triple-class refractory (fourth line and later). Moving from the current fourth-line indication to third-line therapy removes the triple-class refractory requirement, significantly expanding the addressable patient population and enables physicians to treat patients earlier in their disease.

"The positive CHMP opinion paves the way for broader patient access and expanded commercial opportunities across Europe," says **Sofia Heigis, CEO of Oncopeptides**. "Expanding into the third line removes the triple-class refractory barrier, effectively doubles our addressable patient population and enables longer treatment duration. If approved by the European Commission, this broader label would significantly unlock potential beyond our current indication and support our path to cash-flow positivity during 2027."

The recommendation is based on clinical evidence from the Phase 3 OCEAN trial, which demonstrated efficacy and safety in patients with relapsed and refractory multiple myeloma (RRMM). As shown in the study, earlier-line treatment allows patients to remain on therapy longer, which is estimated to double the average number of treatment cycles per patient in third line compared to the current indication in fourth line.

Following this positive CHMP opinion, a final decision from the European Commission (EC) is anticipated within 30 to 60 days. Upon EC approval, Oncopeptides will initiate local pricing and reimbursement discussions across Europe. In Germany, existing regulatory frameworks allow for immediate commercial sales under the expanded indication upon submission of the access dossier, which Oncopeptides plans to submit within approximately one month of EC approval.

For more information, including questions and answers for investors, please visit www.oncopeptides.com.

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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 2026-09-17 17:35 CEST.

About Oncopeptides

Oncopeptides is a Swedish biotech company focusing on research, development and commercialization of targeted therapies for difficult-to-treat cancers.

The company uses its proprietary Peptide Drug Conjugate platform (PDC) to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. Its flagship drug is currently being commercialized in Europe with partnership agreements for South Korea, the Middle East and Africa and elsewhere.

Oncopeptides is also developing several new compounds based on its two proprietary technology platforms PDC and SPiKE.

The company was founded in 2000, has about 70 employees with operations in Sweden, Germany, Austria, Spain and Italy. Oncopeptides is listed on Nasdaq Stockholm with the ticker ONCO.

For more information see: www.oncopeptides.com

About Pepaxti

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.

Attachments

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