Press Release
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European Commission approves label expansion of Pepaxti to third-line treatment

STOCKHOLM — November 9, 2026 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on difficult-to-treat cancers, today announced that the European Commission (EC) has formally approved the Type II variation application for Pepaxti (melflufen). The decision expands the marketing authorization to include adult patients with multiple myeloma who have received at least two prior lines of therapy (third line and later), and whose disease is refractory to lenalidomide and the last line of therapy.

The approval formally confirms the positive opinion issued by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP). By broadening the indication from the prior fourth-line setting to third-line therapy, the requirement for triple-class refractoriness (TCR) is eliminated.

"The formal approval by the EC is a key milestone and allows physicians to prescribe Pepaxti in earlier lines of therapy, providing its' benefit for more patients," **said Sofia Heigis, CEO of Oncopeptides**. "While this formal decision was anticipated following CHMP's recommendation, its strategic importance cannot be overstated. The broadened indication has the potential to double the addressable patient base, and enable longer as well as removing the TCR requirement. Utilizing the commercial footprint we already have in place, we are able to scale Pepaxti cost-effectively in our key markets, supporting our ambition to become cash flow positive during 2027."

The milestone unlocks significant strategic and commercial value for Oncopeptides across Europe:

- **Doubles addressable patient population:** Removing the triple-class refractory barrier effectively doubles the number of eligible patients across Europe who can benefit from earlier intervention.
- **Longer treatment duration:** As demonstrated in the Phase 3 OCEAN trial, earlier-line treatment allows patients to stay on therapy longer, effectively doubling the average number of treatment cycles per patient in third line compared to fourth-line treatment.
- **Substantially expands commercial upside:** The combination of an expanded patient cohort and extended treatment duration unlocks new revenue potential.
- **Supports path to profitability:** Leveraging existing commercial infrastructure in our key markets allows cost-efficient scaling, reinforcing the company's trajectory toward achieving positive cash flow during 2027.

Oncopeptides is now progressing its market access and commercialization roadmap:

- **Launch in Germany:** Oncopeptides plans to submit its access dossier within approximately one month, which permits immediate commercial sales in the third-line setting while benefit assessment followed by pricing negotiations are underway.

- **Maintain innovative pricing:** A 'basket' approach averaging modern third-line therapies is today being used in Germany. This updated framework establishes an attractive comparative price anchor that potentially protects Pepaxti's innovative value.
- **Broader European rollout:** Formal pricing and reimbursement procedures will proceed across Oncopeptides' other key markets, including Spain and Italy, following local submission schedules. The company is also in the process of investigating how the new label could be leveraged in additional markets, in order to realize the full European potential.

The expanded indication is supported by robust clinical data from the Phase 3 OCEAN trial and safety data from several clinical trials and the real world, evaluating Pepaxti plus dexamethasone in relapsed and refractory multiple myeloma (RRMM).
The data set established both efficacy and safety in this setting and confirms that earlier intervention with Pepaxti can enable longer disease control and prolonged treatment duration.

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 2026-11-09 12:58 CET.

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 two prior lines of therapies, whose disease is refractory to lenalidomide and the last line of 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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