Press Release
11 May 2026 08:15:00 CEST

Oncopeptides intends to submit type II variation to expand Pepaxti label to include third line treatment

STOCKHOLM — May 11, 2026 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on difficult-to-treat cancers, today announces its intention to submit a Type II variation application to the European Medicines Agency (EMA). The submission follows an updated assessment of the evolving therapeutic and regulatory landscape in Europe. An approved application for a broader indication would significantly expand the potential addressable market for Pepaxti.

A broader indication including third line patients would double the addressable patient population for Pepaxti in Europe. In addition, third line patients are also estimated to undergo, on average, double the number of treatment cycles compared to the current label. Oncopeptides has previously communicated a SEK 1.5 billion potential for Pepaxti in the European market, reflecting the current indication (fourth treatment cycle and onwards). Oncopeptides assesses that the potential regulatory approval followed by subsequent market access could unlock significant added potential for sales of Pepaxti in Europe.

"As more drugs have entered the markets across Europe, the treatment landscape has developed and now allows us to pursue an indication in earlier lines of therapy giving access to a broader population," says **Sofia Heigis, CEO of Oncopeptides**. "Market experience from the use of Pepaxti has generated positive clinical experience confirming the unmet need for a PDC as a complement to immunotherapy."

The submission is supported by clinical data from the Phase 3 study OCEAN and seeks to expand the therapeutic indication of Pepaxti (melflufen) to include adult patients with multiple myeloma who have received at least two prior lines of therapies (3L+), and whose disease is refractory to lenalidomide and the last line of therapy.

Oncopeptides intends to submit the application during the coming months and expects first regulatory feedback before end of this year with a subsequent final decision by the European Commission in H1 2027.

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

Webcast for investors
The company will host a webcast and Q&A session aimed at investors, analysts and media on May 11 at 12:00 CET.

If you wish to participate via webcast, please use the link below.
https://oncopeptides.events.inderes.com/investor-call-2026

If you wish to participate via teleconference, please register on the link below. After registration you will be provided phone numbers and a conference ID to access the conference. You can ask questions verbally via the teleconference.
https://events.inderes.com/oncopeptides/investor-call-2026/dial-in

For more information, please contact:

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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 2026-05-11 08:15 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 80 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

Oncopeptides intends to submit type II variation to expand Pepaxti label to include third line treatment