Press Release
12 June 2026 12:59:00 CEST

Oncopeptides submits Type II variation application to EMA for Pepaxti label expansion into third line treatment

STOCKHOLM — June 12, 2026 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on difficult-to-treat cancers, today announces that it has formally submitted its Type II variation application to the European Medicines Agency (EMA). The application has been successfully validated, and the official regulatory procedure is scheduled to start on June 20, 2026.

The submission, which the company previously has announced its' intention to submit, 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 (3rd line+), and whose disease is refractory to lenalidomide and the last line of therapy. Currently, Pepaxti is indicated for adult patients who have received at least three prior lines of therapies and are triple-class refractory (4th line+).

The potential approval for this broader indication would address an important medical need and strengthen the position of Pepaxti in the treatment landscape for relapsed, refractory multiple myeloma (RRMM). An approved application would significantly expand the potential addressable market for Pepaxti, doubling the current addressable patient population in Europe. In addition, third-line patients are estimated to undergo, on average, double the number of treatment cycles compared to the current label, potentially driving a powerful clinical and commercial multiplier effect.

Based on standard regulatory procedures and the successful validation of the file, Oncopeptides expects to receive a CHMP (Committee for Medicinal Products for Human Use) opinion between September and November 2026. Following a positive CHMP opinion, a final European Commission (EC) decision is anticipated within 30 to 60 days.

The company's previously communicated European market potential of SEK 1.5 billion reflects only the current fourth-line indication and does not include the substantial added commercial potential that a third-line approval would unlock.

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

For more information, please contact:

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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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