

Oncopeptides receives decision from the U.S. Food and Drug Administration confirming withdrawal of Pepaxto from the U.S. market

Stockholm – February 23, 2024 – Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces that the U.S. Food and Drug Administration (FDA) has made a decision regarding the withdrawal of Pepaxto, which Oncopeptides had appealed.

In their decision, the FDA concludes that they have determined that the grounds for withdrawing the approval have been met. The full decision is, or will momentarily be, available in the public docket created by the FDA through the [following link](#). Oncopeptides will now thoroughly assess the decision.

Oncopeptides' focus remains on commercialization in Europe where the company has a full marketing authorization.

For more information, please contact:

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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

[Oncopeptides receives decision from the U.S. Food and Drug Administration confirming withdrawal of Pepaxto from the U.S. market](#)