

Oncopeptides' Pepaxti has been granted marketing authorization in the UK

STOCKHOLM — November 11, 2022 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on research and development of therapies for difficult-to-treat hematological diseases, today announces that Pepaxti® (melphalan flufenamide, also called melflufen) has been granted marketing authorization in combination with dexamethasone, by the Medicines & Healthcare products Regulatory Agency, MHRA, in UK.

“The approval of Pepaxti in UK is one additional important milestone for Oncopeptides that further validates our science and data,” says Jakob Lindberg, CEO Oncopeptides AB. “Pepaxti provides clinical benefit to patients with triple class refractory disease. This is very good news for patients with multiple myeloma, whose treatment options ultimately become exhausted.”

The marketing authorization in the UK is based on data from the phase 2 HORIZON study and is supported by data from the randomized controlled phase 3 OCEAN study as a confirmatory study.

The clinical benefit of melflufen in multiple myeloma patients with a treatment history with no stem-cell transplant or a successful prior stem-cell transplant has recently gained additional support with data from the phase 3 LIGHTHOUSE study.

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.

On August 18, Pepaxti was granted marketing authorization by the European Commission in EU and in the EEA-countries Iceland, Lichtenstein, and Norway.

Multiple myeloma is an incurable disease that mainly affects people over 65 years of age. Data from Cancer Research UK (Cancer Research UK, 2010) and the Global Cancer Observatory (Globocan, 2020) states that the estimated prevalence of multiple myeloma is around 17.600 patients. There are around 6.000 new cases diagnosed every year.

Oncopeptides is currently assessing the market access opportunities for Pepaxti in the UK.

For more information, please contact

Global Head of Corporate Communications, Oncopeptides AB (publ)

E-post: rolf.gulliksen@oncopeptides.com

Mobil: + 46 70 262 96 28

The information in the press release 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 person above, on November 11, 2022, at 17:15 (CET).

About Pepaxti

Pepaxti (melphalan flufenamide, also called melflufen) is a lipophilic peptide conjugated alkylating drug that rapidly and selectively is delivering cytotoxic agents into tumor cells. The drug is composed of a di-peptide and an alkylating moiety. The lipophilicity allows a faster cellular uptake whereas the peptide hydrolysis mediated by aminopeptidases, results in accumulation of alkylating moieties in cancer cells. This results in an improved efficacy without an increased toxicity compared to melphalan. Pepaxti inhibits proliferation and induces apoptosis of haematopoietic and solid tumour cells. It shows synergistic cytotoxicity in combination with dexamethasone in melphalan resistant and non-resistant multiple myeloma cell lines.

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About Oncopeptides

Oncopeptides is a global biotech company focused on research and development 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. On August 18, 2022, the European Commission granted Pepaxti[®] (melphalan flufenamide, also called melflufen) Marketing Authorization in the European Union and countries in the European Economic Area, 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.

Oncopeptides is developing several new compounds based on its technology platforms. The company is built on a Swedish innovation and is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. More information is available on www.oncopeptides.com.