Stockholm, Sweden **Press release August 18, 2022**

European Commission approves Oncopeptides' Pepaxti for the treatment of patients with relapsed refractory multiple myeloma

STOCKHOLM — August 18, 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 the European Commission has granted Pepaxti® (melphalan flufenamide, also called melflufen) marketing authorization 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. The marketing authorization is valid in all EU member states, as well as in the European Economic Area (EEA) countries Iceland, Lichtenstein, and Norway.

The marketing authorization is based on data from the phase 2 HORIZON study and is supported by data from the randomized controlled phase 3 OCEAN study as confirmatory study. Oncopeptides intends to submit a type II variation in Q4 2022 to enable access to earlier lines of treatment for patients with relapsed refractory multiple myeloma (RRMM).

"The approval of Pepaxti in Europe is foundational for Oncopeptides, and brings excellent news for patients and shareholders," says Jakob Lindberg, CEO Oncopeptides AB. "Despite the introduction of novel therapies, patients with triple class refractory disease have a high unmet medical need, since their treatment options ultimately become exhausted."

Oncopeptides will now advance market access activities to pave the way for a successful launch of Pepaxti in Germany in Q4, 2022. The Company is dedicated to making the drug available for patients across Europe and is actively considering various options to commercialize the product.

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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 August 18, 2022, at 13:00 (CET).

About HORIZON study

The HORIZON study is a pivotal phase 2 study, that evaluated melflufen in combination with dexamethasone, in heavily pre-treated patients with poor prognosis. This multi-center single arm study evaluated 157 patients with relapsed or refractory multiple myeloma, of whom 97 were triple-class refractory and had received at least four prior lines of treatment. The efficacy results for triple-class refractory patients who have received at least 3 prior lines of therapies and who had no ASCT or progressed more than 36 months after an ASCT in the HORIZON study is outlined below:

Response (n=52)	HORIZON study (assessed by investigator)
Overall response rate (ORR), 95% CI (%)	28.8% (17.1%, 43.1%)
Duration of response (DOR) 95% CI (months)	7.6 (3.0-12.3)
Time to response (TTR) (months)	2.3 (1.0-10.5)

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 hematopoietic and solid tumor cells. It shows synergistic cytotoxicity in combination with dexamethasone in melphalan resistant and non-resistant multiple myeloma cell lines.

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 therapy, 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 therapies. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation.

About Multiple Myeloma

Multiple myeloma is a cancer that originates in plasma cells, a type of white blood cells which produce antibodies to help fight infection, and cause cancer cells to accumulate in the bone marrow. Multiple Myeloma is the second most common hematologic malignancy, and accounts for approximately 1-2% of all new cancer cases, with a global incidence rate of 1.7 per 100,000 and an age-standardized incidence rate of 2.1-3.4 per 100,000 in France, Germany, Italy, Spain, and the UK. An estimated 35,842 patients were diagnosed in the EU27 during 2020, with an estimated 23,275 deaths due to the disease (ECIS 2020).

Patients with multiple myeloma may have symptom-free periods, but the disease always relapses, and patients may become refractory to all available treatment options due to mutations and/or clonal evolution of the tumor cells. A growing subset of patients are triple-class refractory, and develop disease refractory to immunomodulatory drugs, proteasome inhibitors, and CD38- targeting monoclonal antibodies. These patients have a very short expected overall survival.

About Oncopeptides

Oncopeptides is a biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary PDC platform to develop peptide-drug conjugated compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. The first drug coming from the PDC platform, Pepaxto® (INN melphalan flufenamide), also called melflufen was granted accelerated approval in the U.S., on February 26, 2021, in combination with dexamethasone, for treatment of adult patients with relapsed or refractory multiple myeloma. The Company voluntarily withdrew the drug on October 22, 2021, and then rescinded the withdrawal on January 21, 2022. Due to regulatory hurdles the product is currently not marketed in the U.S. On June 23, 2022, the CHMP adopted a positive opinion recommending full approval of Oncopeptides Pepaxti® (melphalan flufenamide), in the EU in patients with triple class refractory multiple myeloma.

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