Stockholm, Sweden **Press release June 23, 2022**

CHMP issues a positive opinion recommending full approval of Oncopeptides Pepaxti in EU for patients with triple class refractory multiple myeloma

STOCKHOLM — June 23, 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 Medicines Agency´s (EMA) Committee for Medicinal Products for Human Use (CHMP), has unanimously adopted a positive opinion recommending a full marketing authorization approval (MAA) of Pepaxti® (melphalan flufenamide, also called melflufen) in EU. The European Commission (EC) will make a legally binding decision based on the EMA recommendation within 60 days. Once granted by EC, 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 positive opinion is based on data from the phase 2 HORIZON study and is supported by data from the randomized controlled phase 3 OCEAN study which was utilized as confirmatory study. No specific post-marketing commitments were issued. 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).

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.

“Pepaxti helps patients with multiple myeloma, an incurable hematologic cancer. Today’s positive CHMP opinion confirms that Pepaxti provides benefit to these patients and is foundational for the future of Oncopeptides and our development pipeline,” says Jakob Lindberg, CEO of Oncopeptides. “Based on the scientific evaluation by EMA, our dialogue with the US Food and Drug Administration (FDA) has now been intensified to achieve a clear path forward also for US patients.”

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

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)

“The recommendation for full approval of Pepaxti by EMA is really good news for patients with triple class refractory disease, where the unmet medical need remains high and treatment options often are exhausted,” says Pieter Sonneveld, professor of Hematology at the Erasmus University Medical Center in Rotterdam, the Netherlands and principal investigator of the OCEAN study.

“EMA´s assessment of Pepaxti corroborates our scientific conclusion that the overall survival result in the OCEAN study constitutes a case of true survival heterogeneity which is reflected in the indication statement in accordance with the agency´s guidelines,” says Klaas Bakker, MD, PhD, Executive Vice President, and Chief Medical Officer. “In addition, EMA confirms that there are no toxicological safety signals in both studies and there is a positive benefit risk profile in the indicated patient population. The non-transplanted, often older patient population, which represents the largest group of RRMM patients, particularly benefits from treatment with Pepaxti.”

As previously disclosed, Oncopeptides has an EIB loan facility. Oncopeptides and EIB are currently in negotiations, to update tranche definitions to reflect the current regulatory situation. In addition, the Company is considering additional financing options to capture the opportunities with the upcoming EU-approval. This may include new share issues and other public or private financing options.

Oncopeptides will advance market access activities after an approval by the European Commission, to pave the way for a successful launch of Pepaxti in Germany in Q4, 2022. The Company is actively considering various options to commercialize the drug, making it available for patients across Europe, and maximizing shareholder value.

Conference call for investors, analysts, and media

Investors, financial analysts, and media are invited to participate in a webcast with a Q&A session on June 27, 2022, at 11:00 (CET). The event will be hosted by CEO Jakob Lindberg, CMO Klaas Bakker and CFO Annika Muskantor.

Webcast

The webcast will be streamed via https://tv.streamfabriken.com/2022-pressconference.
The link can also be found on the website: www.oncopeptides.com.

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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 June 23, 2022, at 17:55 (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 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 pharmaceuticals for difficult-to-treat haematological 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), 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. Due to regulatory hurdles the product is currently not marketed in the U.S. On June 23, 2022, CHMP adopted a positive opinion recommending full approval of Oncopeptides Pepaxti® (melphalan flufenamide), in EU in patients with triple class refractory multiple myeloma. Oncopeptides is developing several new compounds based on the PDC platform. The company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. More information is available on www.oncopeptides.com.