Stockholm, Sweden **Press release October 12, 2020**

With the priority review underway at FDA, Oncopeptides moves forward with intent to file for conditional approval of melflufen with EMA

STOCKHOLM — October 12, 2020 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO) today announces that the Company has informed the European Medicines Agency, EMA, about its intention to submit an application for a conditional marketing authorization of melflufen (INN melphalan flufenamide) in the EU, based on the pivotal phase 2 HORIZON study in relapsed refractory multiple myeloma (RRMM).

The decision to submit an application for conditional approval has been grounded on an in-depth analysis of the regulatory environment and is endorsed by key opinion leaders in the EU. Previously the Company intended to await the results from the ongoing randomized, phase 3 OCEAN study before submitting an application for marketing authorization. Upon completion, the outcome from the OCEAN study comparing melflufen and pomalidomide in patients with RRMM, will be submitted to regulatory authorities to potentially expand the label of melflufen.

The HORIZON study demonstrates that melflufen in combination with dexamethasone has a potential to provide a therapeutic option for patients with RRMM that are hard to treat and have a poor prognosis, including patients with triple-class refractory myeloma and patients with extramedullary disease (EMD).

"Key opinion leaders and clinics across Europe have gained extensive experience of melflufen from our clinical development program in multiple myeloma. We share a mutual interest to enable early access to this rapidly growing patient population in desperate need of new treatment options", says Klaas Bakker, CMO of Oncopeptides.

According to the European Medicines Agency, medicines are eligible for conditional approval if they are aimed at treating or preventing seriously debilitating or life-threatening diseases. Conditional marketing authorizations may be granted if; the benefit-risk balance of the product is positive, comprehensive data can be provided, there is an unmet medical need, and the benefit to public health of making the product available outweighs the risks due to need for additional data.

The US Food and Drug Administration, FDA, has granted priority review to Oncopeptides´ New Drug Application of melflufen in combination with dexamethasone for treatment of patients with multiple myeloma. The FDA has set a target date for the review of the New Drug Application, to February 28, 2021.

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The information was submitted for publication on October 12, 2020 at 08:00 (CET).

About melflufen

Melflufen (INN melphalan flufenamide) is a first in class peptide-drug conjugate (PDC) that targets aminopeptidases and rapidly releases alkylating agents into tumor cells. Melflufen is rapidly taken up by myeloma cells due to its high lipophilicity and is immediately hydrolyzed by peptidases to release an entrapped hydrophilic alkylator payload. Aminopeptidases are overexpressed in tumor cells and are even more pronounced in advanced cancers and tumors with a high mutational burden. In vitro, melflufen is 50-fold more potent in myeloma cells than the alkylator payload itself due to the increased intracellular alkylator concentration. Melflufen displays cytotoxic activity against myeloma cell lines resistant to other treatments, including alkylators, and has also demonstrated inhibition of DNA repair induction and angiogenesis in preclinical studies. In the pivotal phase 2 HORIZON study melflufen plus dexamethasone demonstrated encouraging efficacy and a clinically manageable safety profile in heavily pretreated patients with relapsed refractory multiple myeloma, with primarily hematologic Adverse Events (AE) and a low incidence of non-hematologic AEs.

About Oncopeptides

Oncopeptides is a pharmaceutical company focused on the development of targeted therapies for difficult-to-treat hematological diseases. The company is focusing on the development of the lead product candidate melflufen, a first in class peptide-drug conjugate (PDC) that targets aminopeptidases and rapidly releases alkylating agents into tumor cells. Melflufen (INN melphalan flufenamide) is in development as a new treatment for the hematological malignancy multiple myeloma and is currently being tested in multiple clinical studies including the pivotal phase 2 HORIZON study and the ongoing phase 3 OCEAN study. Based on the results from the HORIZON study Oncopeptides has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration, FDA, for accelerated approval of melflufen in combination with dexamethasone for treatment of adult patients with triple-class refractory multiple myeloma. Oncopeptides´ global Headquarters is in Stockholm, Sweden and the U.S. Headquarters is situated in Boston, Mass. The company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. More information is available on www.oncopeptides.com.