

Oncopeptides enrolls the first patient in the phase 3 LIGHTHOUSE combination study in multiple myeloma

STOCKHOLM — December 21, 2020 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), today announced that the first patient has been dosed in the phase 3 LIGHTHOUSE study, evaluating the efficacy and safety of a triple combination therapy with melflufen plus dexamethasone and subcutaneous daratumumab compared to daratumumab alone. The phase 3 LIGHTHOUSE study is a randomized, open-label study in patients with relapsed refractory multiple myeloma who are refractory to an immunomodulatory agent and a proteasome inhibitor or who have had at least three prior lines of therapy, including these agents.

“Following the encouraging results of our ANCHOR study this is an important study to further evaluate the potential role of melflufen in triplet regimens”, says Klaas Bakker, MD, PhD, Chief Medical Officer, Oncopeptides AB. “There is an imminent need for additional therapeutic options as myeloma patients become multi-resistant earlier in their treatment journey. A positive outcome may potentially support the use of melflufen as combination therapy with daratumumab in earlier stages of multiple myeloma”.

Additional study information can be found on <https://clinicaltrials.gov/>, identifier: NCT04649060.

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The information was submitted for publication on December 21, 2020 at 16:45 (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 lead product candidate melflufen, is a first in class peptide-drug conjugate that targets aminopeptidases and rapidly releases alkylating agents into tumor cells. Melflufen is in development as a new treatment for the hematological malignancy multiple myeloma and is 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 a New Drug Application has been submitted 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. The FDA, has granted the New Drug Application a priority review, with a PDUFA date of February 28, 2021. 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.