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Oncopeptides presents new data from phase 2 ANCHOR combination study in multiple myeloma at American Society of Hematology meeting ASH

STOCKHOLM — December 6, 2020 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a pharmaceutical company focused on the development of targeted therapies for difficult-to-treat hematological diseases today announces updated efficacy and safety data from the ongoing phase 2 ANCHOR combination study, following an oral presentation at the 62nd American Society of Hematology virtual annual meeting. The data showed that a triplet regimen with melflufen (INN melphalan flufenamide) plus dexamethasone in combination with daratumumab or bortezomib in heavily pretreated patients with relapsed refractory multiple myeloma, demonstrated encouraging activity, was well tolerated and had a similar safety profile as when used as a doublet regimen with only melflufen plus dexamethasone. The severe treatment related adverse events reported were primarily hematologic and were clinically manageable with dose reduction.

The primary objective of the phase 2 ANCHOR study is overall response rate, and a secondary objective is progression free survival. The data represents an analysis of both treatment arms, with a cut-off date of October 19, 2020. The overall response rate for melflufen plus dexamethasone was 73% in combination with daratumumab and 62% in combination with bortezomib. The median progression free survival was 12.9 months when combined with daratumumab. The recommended dose of melflufen for future studies with daratumumab shall be 30 mg. Since the bortezomib arm of ANCHOR still is recruiting, progression free survival has not been reported and the recommended phase 2 dose is yet to be determined. The recruitment is expected to be completed in 2021.

"The ANCHOR data are very promising: both combinations are well tolerated and demonstrated encouraging activity. The data support further development of melflufen in triplet regimens", says Klaas Bakker, MD, PhD, Chief Medical Officer, Oncopeptides AB. "This provides a clear rational for our larger randomized phase 3 LIGHTHOUSE study, which compares melflufen and dexamethasone with subcutaneous daratumumab vs. subcutaneous daratumumab alone. We are preparing study start in close dialogue with relevant authorities and expect to enroll the first patient during the first quarter of 2021".

ANCHOR is a phase 1/2 open label multicenter study evaluating the safety and efficacy of melflufen plus dexamethasone in combination with either daratumumab or bortezomib in patients with relapsed refractory multiple myeloma, who have undergone 1-4 prior lines of therapy. The patients are refractory to an immunomodulatory drug and/or a proteasome inhibitor. They have not received any prior anti-CD38 monoclonal antibody therapy.

The presentation is posted on our website. A link can be found here: www.oncopeptides.com/presentations

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The information was submitted for publication on December 6, 2020 at 22:40 (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.