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Oncopeptides initiates the first study with melflufen outside multiple myeloma and enrolls the first patient in the phase 1/2 AL amyloidosis study

STOCKHOLM — August 7, 2020 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO) announced today that the first patient has been enrolled in the Immunoglobulin Light Chain (AL) amyloidosis (OP201) study. This open-label, phase 1/2 study of melflufen and dexamethasone for patients with AL amyloidosis, following at least one prior line of therapy, is the first study to explore the effect of melflufen outside of multiple myeloma.

"Today we embarked upon the next phase of our journey with melflufen as we initiated patient enrollment in our phase 1/2 AL amyloidosis study," says Klaas Bakker, CMO of Oncopeptides. "This study will build upon the promising pre-clinical data that we presented at ASH in December of 2019. With a median overall survival of only three and a half years from diagnosis, we hope to see melflufen providing benefit for patients in this clinical setting where new treatment options are desperately needed."

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About AL amyloidosis

Amyloidosis describes a highly heterogenous collection of diseases that involve some form of protein deposition in one or several organs. Patients with light chain (AL) amyloidosis suffer from a clonal plasma-cell disease, usually a monoclonal gammopathy of unknown significance (MGUS) or more rarely, myeloma. It is a rare disease that occurs in about 30,000 to 45,000 patients in the U.S. and Europe. Current treatment alternatives are limited to a median overall survival of 3.5 years.

About the OP201 AL amyloidosis study

The AL amyloidosis study is an open-label, phase 1/2 dose-escalation and dose-expansion study of melflufen and dexamethasone in patients with Immunoglobulin Light Chain (AL) amyloidosis following at least one prior line of therapy. The study will enroll approximately 40 patients. The primary endpoints in the phase 1 part are safety and tolerability, and in the phase 2 part of the trial Overall Response Rate (ORR). For more information see: https://clinicaltrials.gov/ct2/show/NCT04115956?term=melflufen&rank=4

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 deliver an entrapped hydrophilic alkylator payload. Peptidases play a key role in protein homeostasis and feature in cellular processes such as cell-cycle progression and programmed cell death. 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 (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' headquarters is in Stockholm, Sweden with its U.S. headquarters 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.