

Oncopeptides completes the extended enrollment for the pivotal phase 3 OCEAN study in relapsed refractory multiple myeloma – 495 patients included

STOCKHOLM — September 4, 2020 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO) today announces that the last patient has been successfully enrolled in the pivotal phase 3 study OCEAN in relapsed refractory multiple myeloma (RRMM). The original enrollment target of 450 patients was reached in May 2020, but an analysis indicated that patients were staying longer on treatment than initially estimated. Thus, a decision was made to leave recruitment open to ensure that the number of disease progression events needed to complete the study would be reached within a reasonable timeframe. An additional 45 patients have now been recruited. The company has closed enrollment and reiterates that the topline results will be available in the first half of 2021.

OCEAN is a randomized, comparative study between melflufen (INN melphalan flufenamide), and pomalidomide in patients with RRMM. The study was initiated in 2017 and today includes 495 patients from more than 100 hospitals around the world. The patients have previously been treated with at least an immunomodulator (IMiD) and a proteasome inhibitor (PI) and have all developed resistance to their last line of therapy and to lenalidomide (IMiD), the most commonly used multiple myeloma drug. The primary endpoint of the phase 3 OCEAN study is Progression Free Survival. The data will be evaluated once 339 patients have progressed in their disease.

“This is very exciting news. Thanks to the dedicated participation from patients, investigators and study teams around the world, we have managed to reach our extended enrollment target faster than anticipated, despite these challenging times”, says Marty J Duvall, CEO of Oncopeptides AB. “I am really impressed by the journey that Oncopeptides has made ever since the study start in 2017, from being a small Stockholm based R&D company, to becoming a fully- fledged, integrated, global biopharma company, preparing the first commercial launch”.

The U.S. Food and Drug Administration, FDA, has recently granted priority review for Oncopeptides’ New Drug Application seeking approval of melflufen in combination with dexamethasone for the treatment of adult patients with triple class refractory multiple myeloma. The decision was based on the results from the ongoing pivotal phase 2 study HORIZON, evaluating melflufen in RRMM patients.

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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.