Oncopeptides starts the phase 2 PORT study comparing peripheral versus central administration of melflufen and dexamethasone in multiple myeloma

STOCKHOLM — August 4, 2020 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO) today announced that the first patient has been enrolled in the phase 2 PORT study. The study, which is expected to be fully recruited in December 2020, is an open-label, randomized, cross-over study which compares safety, tolerability and efficacy of peripheral or central intravenous administration of melflufen in combination with dexamethasone in patients with relapsed refractory multiple myeloma, RRMM. Up to 25 RRMM patients who have received at least two previous lines of therapy will be enrolled.

“Patients who receive anti-cancer treatment often get an implanted port, a type of central venous catheter placed under the skin, to limit the number of needle sticks, facilitate intravenous administration and enhance convenience. The PORT study may provide an additional option in the way melflufen is delivered”, says Klaas Bakker, CMO of Oncopeptides. “Broadening the mode of administration would allow physicians to choose the option that is preferable for their patients”.

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The information in the press release is information that Oncopeptides is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons above, on August 4, 2020 at 15.30 (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. 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 (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](http://www.oncopeptides.com).