

New analysis confirms that multiple myeloma patients in the OCEAN study stay on treatment longer than previously estimated - results expected H1-2021

STOCKHOLM — June 1, 2020 — Oncopeptides AB (Nasdaq Stockholm: ONCO) announces that patients in the OCEAN study stay on treatment longer than previously estimated. As a consequence, top-line results are estimated for H1 2021 instead of previously communicated Q4 2020. Patient recruitment in OCEAN will remain open to ensure that the 339 disease progression events needed to complete the study can be reached within a reasonable timeframe.

OCEAN is a randomized, comparative study between melflufen and pomalidomide in patients with relapsed refractory multiple myeloma (RRMM). The patients enrolled in the study 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 drug for the treatment of multiple myeloma. The primary endpoint of the phase 3 study is Progression Free Survival (PFS). The results will be evaluated once 339 patients have progressed in their disease.

“A recent analysis indicates that patients enrolled in the OCEAN-study continue treatment for a longer period of time than originally estimated, which speaks to the potential benefit patients can have by participating in this trial”, says Jakob Lindberg, CEO of Oncopeptides. “However, this most likely increases the time required to reach the number of disease progression events needed to complete the study. We will continue patient enrollment to enable an analysis of results within a reasonable timeframe.”

Oncopeptides is preparing an application for accelerated approval in Q2 2020 based on the results from the ongoing pivotal phase 2 study HORIZON, evaluating melflufen in RRMM patients. Data from the pivotal phase 3 study OCEAN, will form the basis for a submission of a supplemental New Drug Application (sNDA) to the US FDA in H2 2021, followed by a submission of a Marketing Authorization Application (MAA) in Europe.

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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 person above, on June 1, 2020 at 08.00 (CET).

About melflufen

Melflufen (melphalan flufenamide) is a first-in-class anti-cancer peptide-drug conjugate that rapidly delivers an alkylating payload into tumor cells. Melflufen is rapidly taken up by myeloma cells due to its high lipophilicity and is immediately cleaved 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.

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 (melphalan flufenamide), a first-in-class anti-cancer peptide-drug conjugate that rapidly delivers an alkylating payload into tumor cells. Melflufen is in development as a new treatment for the hematological cancer multiple myeloma and is currently being evaluated in multiple clinical studies including the pivotal phase 2 HORIZON study and the ongoing phase 3 OCEAN study. Oncopeptides' headquarters is in Stockholm, Sweden with 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.