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Press release May 22, 2020

Oncopeptides completes enrollment to the pivotal phase 3 study OCEAN for relapsed refractory multiple myeloma - 450 patients included

STOCKHOLM — May 22, 2020 — Oncopeptides AB (Nasdaq Stockholm: ONCO) announces a successful completion of enrollment in the pivotal phase 3 study OCEAN for the treatment of relapsed refractory multiple myeloma. The study includes 450 patients from more than 100 hospitals around the world. Top line results are expected to be presented later this year.

OCEAN is a randomized, comparative study between melflufen and pomalidomide in patients with relapsed refractory multiple myeloma (RRMM). The patients have been treated with immunomodulatory inhibitors (IMiD) and proteasome inhibitors (PI), they have developed resistance to their last line of therapy and are refractory to lenalidomide (IMiD), the most commonly used drug for the treatment of multiple myeloma. The primary endpoint is Progression Free Survival (PFS).

“I am very pleased to announce that we managed to complete enrollment in the OCEAN study despite the strenuous situation that our research and healthcare providers currently are facing. A positive OCEAN comparison between melflufen and the standard of care in RRMM will provide critical insights on how to optimize treatment of RRMM patients,” says Jakob Lindberg, CEO of Oncopeptides. “This comparison will enable us to file for label expansion of melflufen in the US and submit for regulatory approval in the EU and the rest of world”.

As previously communicated 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. Recently announced topline results from HORIZON demonstrate an Overall Response Rate of 26 % in triple-class refractory patients.

Oncopeptides expects to present top line results from OCEAN later this year. Based on these pivotal phase 3 data, the Company intends to submit a supplemental New Drug Application (sNDA) to the US FDA in Q2 2021, followed by a submission of a Marketing Authorization Application (MAA) in Europe.

For more information, please contact:

Jakob Lindberg, CEO of Oncopeptides

E-mail: jakob.lindberg@oncopeptides.com

Telephone: +46 8 615 20 40

Rein Piir, Head of Investor Relations at Oncopeptides

E-mail: rein.piir@oncopeptides.com

Cell phone: +46 70 853 72 92

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 May 22, 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, a first-in-class anti-cancer peptide-drug conjugate that rapidly delivers an alkylating payload into tumor cells. Melflufen (melphalan flufenamide) 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.