

Updated results from phase 3 OCEAN study shows melflufen met primary endpoint of superior PFS – Overall Survival data lead to partial clinical hold

STOCKHOLM — July 8, 2021 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a global biotech company focused on the development of therapies for difficult-to-treat hematological diseases, today announces updated results and safety measures based on the head-to-head phase 3 OCEAN study evaluating the efficacy and safety of melflufen (INN melphalan flufenamide) plus dexamethasone versus pomalidomide plus dexamethasone in patients with relapsed refractory multiple myeloma who have received 2 – 4 prior lines of therapy. The randomized study was initiated in 2017 and includes 495 patients from more than 100 hospitals in 21 countries around the world. The topline results were announced on May 25th.

The updated OCEAN results follow a blinded reassessment by the Independent Review Committee (IRC). During the preparations of the clinical study report and regulatory documents it became apparent that the IRC was not provided with all the information available in the clinical database during the time of their initial assessment. This led to a thorough investigation of all 495 patients where a comparison was made between the data provided to the IRC and what data was available in the clinical database. Consequently, data from 29 patients had to be reassessed. In the final analysis melflufen met the primary endpoint of superior Progression Free Survival (PFS) compared to pomalidomide with a Hazard Ratio (HR) of 0.792 (95% CI 0.640-0.979, p-value 0.0311) as determined by the IRC.

Overall Survival (OS) was a key secondary endpoint in the OCEAN study. The OS HR was 1.104 (0.846-1.441) in favor of pomalidomide for the Intention to Treat population. Oncopeptides has performed analyses of the OS data and the Company believes that the OS results are primarily explained by substantial HR differences between pre-specified subgroups in both directions.

Based on the observed large differences in overall survival in pre-specified subgroups, the FDA has requested a partial clinical hold of all clinical studies with melflufen, pending further investigation. Oncopeptides will cooperate closely with the FDA to expeditiously perform necessary analysis to fully understand the benefit/risk profile of melflufen and to identify what patients do benefit from treatment with melflufen in earlier lines of therapy in relapsed refractory multiple myeloma.

This update and measures will be presented at a webcast on July 8, 2021, at 11:00 (CET), log in details is available below.

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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 July 8, 2021, at 07:30 (CET).

Webcast for investors, analysts, and the media

The Company will host a webcast on July 8, 2021, at 11:00 (CET) including presentations by CEO Marty J Duvall, CSO Jakob Lindberg, and CMO Klaas Bakker.

The webcast will be streamed via the web link

<https://tv.streamfabriken.com/oncopeptides-pressconference-july-2021>

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About phase 3 OCEAN study

The phase 3 OCEAN study is a global, randomized, head-to-head, open-label study, evaluating the efficacy and safety of melflufen and dexamethasone, versus pomalidomide and dexamethasone in patients with relapsed refractory multiple myeloma who have received 2-4 prior therapies. The patients have previously been treated with at least an immunomodulator agent, and a proteasome inhibitor. They have all developed resistance to their last line of therapy, and within 18 months from the study start to lenalidomide, the most used drug in multiple myeloma. The study was initiated in 2017 and includes 495 patients from more than 100 hospitals around the world. The primary efficacy endpoint is superiority of Progression Free Survival as measured by IRC.

About Oncopeptides

Oncopeptides is a global biotech company focused on the development of targeted therapies for difficult-to-treat hematological diseases. The company uses its proprietary peptide-drug conjugate (PDC) platform to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. The first drug coming from PDC platform, Pepaxto[®] (melphalan flufenamide), has been launched in the U.S., for the treatment of adult patients with relapsed or refractory multiple myeloma. Melphalan flufenamide is evaluated in a comprehensive clinical study program including the global phase 3 studies OCEAN and LIGHTHOUSE. Oncopeptides is developing several new compounds based on the PDC platform. In 2021 the second compound from the PDC platform, OPD5, is expected to enter clinical development.

Oncopeptides has approximately 300 coworkers. The global Headquarters is based 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.

About melphalan flufenamide

Melphalan flufenamide, also known as melflufen, is a first-in-class peptide-drug conjugate that targets aminopeptidases and rapidly releases alkylating agents inside cancer cells. Aminopeptidases are overexpressed in multiple myeloma cells and are associated with advanced disease and tumor mutational burden. Targeting aminopeptidases causes selective activity in cancer cells, sparing healthy cells.

In the US, Pepaxto[®] (melphalan flufenamide) is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.

***Hazard ratio**

The hazard ratio is a measure of the relative risk of an event at each time point during follow-up when receiving melflufen in relation to pomalidomide. A value below 1 indicates a better treatment effect for melflufen, and a value above 1 indicates a better treatment effect for pomalidomide.