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Oncopeptides presents new data from OCEAN and PORT study - abstracts online

STOCKHOLM — August 27, 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 that data from the phase 3 OCEAN study has been accepted as an oral presentation at the upcoming 18th International Myeloma Workshop (IMW), and the abstract is now available online. More comprehensive data will be presented at the IMW-meeting in Vienna on September 11, at 10:00 (CET).

The phase 3 OCEAN study is a head-to-head comparison evaluating the efficacy and safety of melflufen (INN melphalan flufenamide) plus dexamethasone versus pomalidomide plus dexamethasone. Melflufen met its primary endpoint and demonstrated superior Progression Free Survival (PFS) as assessed by the Independent Review Committee (IRC) versus pomalidomide, in patients with relapsed refractory multiple myeloma (RRMM) who are refractory to lenalidomide and have received 2-4 prior lines of therapy, with a Hazard Ratio* (HR) of 0.79, and p-value of 0.03. Overall Survival (OS) was a key secondary endpoint. The HR for OS was 1.10 in favor of pomalidomide in the Intention to Treat (ITT) population. An analysis of factors impacting overall survival is ongoing. The OCEAN abstract is available at;
https://events.jspargo.com/imw21/public/Content.aspx?ID=85452&sortMenu=102000

"I am very pleased that the IMW has accepted our late breaker abstract on the OCEAN study, and I am looking forward to get our data presented to leading multiple myeloma experts", says Klaas Bakker, MD, PhD, Executive Vice President and Chief Medical Officer at Oncopeptides.

At the IMW Oncopeptides will also present data from the phase 2 PORT study, 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 RRMM. The study demonstrates that exposure to melphalan is similar after periferal and central intravenous administration, and that the differences in administration has no clinical consequences. The PORT abstract is available at;
https://events.jspargo.com/imw21/public/Content.aspx?ID=85452&sortMenu=102000

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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 all been treated with at least an immunomodulator agent (IMiD), and a proteasome inhibitor (PI). They have developed resistance

to their last line of therapy, and within 18 months from the study start to lenalidomide. The study was initiated in 2017 and includes 495 patients from more than 100 hospitals around the world. The primary efficacy endpoint was superior PFS as measured by the Independent Review Committee (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. The recruitment of new patients to all clinical trials has been temporarily paused by the FDA pending further analysis of the data from the OCEAN-study.

Oncopeptides has approximately 300 coworkers. The global Headquarters is based in Stockholm, Sweden and the U.S. Headquarters is situated in Boston, Massachusetts. The company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. More information about the company 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.