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Oncopeptides presents phase 3 OCEAN study results at the IMW meeting

STOCKHOLM — September 11, 2021 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a global biotech company focused on the development of therapies for difficult-to-treat hematological diseases, today presents data from the phase 3 OCEAN study, a direct head to head comparison of the efficacy and safety of melflufen (INN melphalan flufenamide) plus dexamethasone and pomalidomide plus dexamethasone in patients with relapsed refractory multiple myeloma, (RRMM), who are refractory to lenalidomide and have received 2-4 prior lines of therapy. The data was presented today by Fredrik Schjesvold, Head of Oslo Myeloma Center, Norway, at the 18th International Myeloma Workshop (IMW) in Vienna.

Melflufen met the primary endpoint of superior Progression Free Survival (PFS) as assessed by the Independent Review Committee (IRC), with a median PFS of 6.8 months, compared to 4.9 months for pomalidomide, a Hazard Ratio (HR) of 0.79, and a p-value of 0.03. The results of key secondary endpoints in the Intention to Treat (ITT) population were: Overall Survival (OS), which favored pomalidomide with a HR of 1.10, and Overall Response Rate (ORR), where melflufen had a numerically higher ORR of 33 % compared to 27 % for pomalidomide.

An extensive analysis of data in pre specified subgroups showed that the PFS benefit of melflufen mainly was driven by patients without a prior autologous stem cell transplant (ASCT), with a median PFS of 9.3 months versus 4.6 months and a HR of 0.59, compared to pomalidomide. The OS data in patients with no prior ASCT favored melflufen with a median OS of 21.6 months compared to 16.5 months for pomalidomide with a HR of 0.78. However, the OS results in patients with a prior autologous stem cell transplant favored pomalidomide, with a median OS of 31.0 months versus 16.7 months for melflufen, and a HR of 1.61. This benefit of pomalidomide over melflufen in the ASCT subgroup has contributed to the HR of 1.1 in the ITT population.

Melflufen plus dexamethasone treatment resulted in substantially more grade 3/4 hematologic adverse events, when compared to pomalidomide. These were clinically managable and in line with previous reports but more dose modifications were needed with melflufen when compared to pomalidomide.

On September 2, the FDA announced a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee (ODAC) to occur on October 28, 2021, to discuss the safety findings including overall survival from the OCEAN study as a follow up to the FDA safety alert released on July 28, 2021.

“The oral presentation of OCEAN study results at the IMW meeting represents an important milestone for Oncopeptides", says Marty J Duvall, Chief Executive Officer at Oncopeptides. "We have confidence in the OCEAN data and are working closely with the FDA to address the regulatory situation for Pepaxto®”.

“The efficacy and safety data from the OCEAN study provide new and important insights for the multiple myeloma society”, says Pieter Sonneveld, MD, PhD, Professor of Hematology at the Erasmus University of Rotterdam, and Principal Investigator of the OCEAN study.

"Results from the OCEAN study suggests that melflufen plus dexamethasone may become a potential treatment for patients with lenalidomide-refractory RRMM who have received 2-4 previous lines of therapy and who have not received a prior autologous stem cell transplant, says Fredrik Schjesvold, Head of Oslo Myeloma Center, Oslo, Norway. "These patients represent a highly underserved population".

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Webcast for investors, analysts, and the media

The Company will host a webcast on September 12, 2021, at 16:00 (CET). The webcast will include a presentation by MD, PhD Fredrik Schjesvold, Head of Oslo Myeloma Center, Norway, and presentations by CEO Marty J Duvall, and CMO Klaas Bakker, from Oncopeptides. Call-in details were shared in a press release issued on September 9, and can be found on our website www.oncopeptides.com.

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 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 the PDC platform, Pepaxto® (melphalan flufenamide) has been granted accelerated approval in the U.S., and 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. Melphalan flufenamide is evaluated in a comprehensive clinical study program. Oncopeptides is developing several new compounds based on the PDC platform. The second compound from the PDC platform, OPD5, is ready 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.