Stockholm, Sweden **Press release May 25, 2021**

Phase 3 OCEAN study demonstrates that melflufen is at least as efficacious as pomalidomide, the most used medicine in relapsed refractory multiple myeloma

- **According to the Independent Review Committee Assessment, melflufen was non-inferior to pomalidomide on the primary endpoint of Progression Free Survival (PFS) with a Hazard Ratio favoring melflufen of 0.817 and the median PFS for melflufen was 41% higher than for pomalidomide**
- **According to the Investigator Assessment, melflufen was superior to pomalidomide on PFS with a Hazard ratio favoring melflufen of 0.790 and median PFS for melflufen was 42% higher than for pomalidomide**
- **The Overall Response Rate (ORR) was 32.1% for melflufen, compared to 26.5% for pomalidomide**
- **Melflufen and pomalidomide had similar discontinuation rates for adverse events, and the safety profile of melflufen was in line with previous studies**

STOCKHOLM — May 25, 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 positive topline results from the head-to-head phase 3 OCEAN study evaluating the efficacy and safety of melflufen (INN melphalan flufenamide) versus pomalidomide in patients with relapsed refractory multiple myeloma (RRMM). 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 will be presented at a webcast on May 25, 2021, at 11:00 (CET), log in details is available below.

"Following the accelerated approval of Pepaxto® in the U.S. earlier this year, the positive topline results from the OCEAN study marks another major milestone for Oncopeptides. It is very exciting news for patients and indicates that melflufen has the potential to become part of the standard of care in relapsed refractory multiple myeloma", says Marty J Duvall, Chief Executive Officer at Oncopeptides AB. “By demonstrating that melflufen is at least as efficacious as pomalidomide, we pave the way for a potential use of melflufen in earlier lines of therapy in a substantially larger patient population”.

The PFS, as assessed by the independent review committee, demonstrated a Hazard Ratio* favoring melflufen of 0.817 (95% CI: 0.659-1.012, p=0.0640) for the primary endpoint and shows that melflufen is non-inferior to pomalidomide. The Hazard Ratio for PFS as per investigator assessment was 0.790 (95% CI: 0.639-0.976). In both assessments, the median PFS for the melflufen arm was more than 40% higher than for the pomalidomide arm. The Overall Response Rate for melflufen was 32.1% vs. 26.5% for pomalidomide.

“The efficacy and safety data from the OCEAN study are very encouraging, and the results will be of importance in physicians´ treatment decisions for patients with relapsed and refractory multiple myeloma”, says Pieter Sonneveld, MD, PhD, Professor of Hematology at the Erasmus University of Rotterdam, and Principal Investigator of the OCEAN study. “Melflufen has a unique mode of action, which in addition with its tolerability profile, makes the drug an attractive treatment option for many patients.”

Melflufen and pomalidomide had similar discontinuation rates for adverse events, and the safety profile of melflufen was in line with previous studies and consistent across age subgroups. The Company expects to present complete OCEAN data at an upcoming scientific congress.

"The outcome from the phase 3 OCEAN study is very good news for patients with relapsed refractory multiple myeloma", says Klaas Bakker, MD, PhD, Executive Vice President and Chief Medical Officer at Oncopeptides. "This head-to-head-comparison was a bold study with an optimal design for demonstrating melflufen's true isolated treatment effects. I am truly looking forward to sharing these data with a broader audience, as the OCEAN data clearly show that melflufen may be an important therapeutic option for the increasing number of patients who need more treatment alternatives."

Based on these data, Oncopeptides intends to submit a supplementary New Drug Application to the US Food and Drug Administration FDA, in Q4 2021.

Pepaxto® (melphalan flufenamide, also known as melflufen), in combination with dexamethasone, was granted accelerated approval by the FDA on February 26, 2021, 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.

Melflufen is evaluated in a comprehensive clinical study program. In addition to the phase 3 OCEAN study, Oncopeptides is currently enrolling patients in the phase 3 LIGHTHOUSE study, with the aim to establish the efficacy and safety of a combination therapy with melflufen plus daratumumab compared to daratumumab, based on the successful results from the ANCHOR study, presented at American Society of Hematology in December 2020.

For more information, please contact:

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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 May 25, 2021, at 07:00 (CET).

Webcast for investors, analysts, and the media

The Company will host a webcast on May 25, 2021, at 11:00 (CET), including presentations by CEO Marty J Duvall, CSO Jakob Lindberg, CMO Klaas Bakker, and CFO Anders Martin-Löf.

The webcast will be streamed via the web link

https://tv.streamfabriken.com/oncopeptides-press-conference-2-2021

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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 Progression Free Survival.

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.