

Oncopeptides presents clinical abstracts on melflufen at the 2021 American Society of Clinical Oncology

STOCKHOLM — May 19, 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 three abstracts with data on melflufen (INN melphalan flufenamide) in relapsed refractory multiple myeloma, RRMM, have been accepted by the 2021 American Society of Clinical Oncology, ASCO, and have now been published online. The clinical data presentations include updates on Oncopeptides' ANCHOR and LIGHTHOUSE studies as well as a pooled analysis of the O-12-M1 and HORIZON studies in patients who have been exposed to or become refractory to prior alkylators.

“The phase 1/2 ANCHOR study of melflufen plus dexamethasone in combination with either daratumumab or bortezomib shows encouraging clinical activity in heavily pre-treated patients with relapsed refractory multiple myeloma, and the optimal dose of melflufen has now been established for both regimens,” says Klaas Bakker, MD, PhD, Executive Vice President and Chief Medical Officer, Oncopeptides AB. “We will now complete patient enrolment in the bortezomib arm, while the daratumumab arm is already fully accrued, as presented at the American Hematology Association meeting in December 2020, where updated safety and efficacy data from ANCHOR were presented. The data presented here at ASCO data clearly support further development of melflufen in triplet regimens and reinforce the rationale for the ongoing phase 3 LIGHTHOUSE study, comparing melflufen plus dexamethasone in combination with subcutaneous daratumumab with daratumumab alone.”

Below is a brief description of the abstracts that have been accepted by the ASCO. They will be available online at <https://www.asco.org>, on May 19th at 23:00 (CET).

1. ANCHOR (OP-104): MELFLUFEN PLUS DEXAMETHASONE AND BORTEZOMIB IN RELAPSED/REFRACTORY MULTIPLE MYELOMA PATIENTS

The ANCHOR study determined that the optimal dose of melflufen is 30 mg plus dexamethasone and bortezomib and the results showed clinical activity in heavily pretreated RRMM patients. Recruitment for this study is ongoing and updated data including efficacy and safety will be presented at ASCO.

2. LIGHTHOUSE (OP-108): A PHASE 3 STUDY OF MELFLUFEN IN COMBINATION WITH DEXAMETHASONE AND DARATUMUMAB IN RELAPSED/REFRACTORY MULTIPLE MYELOMA PATIENTS

The phase 3 LIGHTHOUSE study is a randomized, controlled, open-label study of melflufen plus dexamethasone in combination with daratumumab vs daratumumab alone in patients with RRMM previously treated with an immunomodulatory agent and a proteasome inhibitor, similar to the indication for daratumumab monotherapy. The primary objective is superiority of PFS. Key secondary endpoints include ORR (\geq PR), DOR, and safety. Patient recruitment is ongoing with a planned enrolment of 240 patients.

3. A POOLED ANALYSIS OF THE O-12-M1 AND HORIZON STUDIES: MELFLUFEN PLUS DEXAMETHASONE IN RELAPSED/REFRACTORY MULTIPLE MYELOMA PATIENTS (RRMM) WHO ARE EXPOSED OR REFRACTORY TO PRIOR ALKYLATORS

This pooled analysis of the O-12-M1 and HORIZON studies showed that melflufen in combination with dexamethasone showed meaningful efficacy and demonstrated a clinically manageable safety profile in patients with RRMM who had been exposed or become refractory to prior alkylators.

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.

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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.

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.