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Oncopeptides phase 3 OCEAN study published in the Lancet Haematology

STOCKHOLM — January 13, 2022 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on research and development of therapies for difficult-to-treat hematological diseases, today announces that the data from the randomized head-to-head phase 3 OCEAN study, evaluating the efficacy and safety of melflufen (INN melphalan flufenamide) plus dexamethasone versus pomalidomide plus dexamethasone in lenalidomide refractory patients with relapsed refractory multiple myeloma (RRMM) that have received 2-4 prior lines of therapy, have been published in the Lancet Hematology. The OCEAN study was initiated in 2017 and includes 495 patients from 108 hospitals in 21 countries across Europe, North America, and Asia.

In the intention to treat population (ITT) melflufen met the primary endpoint of superior Progression Free Survival (PFS) as assessed by the Independent Review Committee, with a median PFS of 6.8 months, compared to 4.9 months for pomalidomide with a Hazard Ratio (HR) of 0.79 (p-value 0.03). PFS was defined as the time from randomization to confirmed disease progression or death.

"The OCEAN results demonstrates that melflufen improves PFS for lenalidomide refractory RRMM patients who have received two to four prior lines of therapy," says Klaas Bakker, MD, PhD, Executive Vice-President, and Chief Medical Officer at Oncopeptides. "We believe that melflufen may become an important treatment option for patients with RRMM. In that respect, the comprehensive data provide valuable insights to the pending European Medicines Agency´s (EMA) review of melflufen for a potential European approval later this year."

Key secondary endpoints were Overall Response Rate (ORR), Overall Survival (OS) and safety. The ORR, the proportion of patients with a complete or partial response, was 33 % in the melflufen group and 27 % in the pomalidomide group (non-statistically different). The ITT OS HR was 1.10 (non-statistically different). The study showed a highly heterogenous OS HR result with significant statistical interactions between the OS HR result and patient characteristics such as Autologous Stem Cell Transplant (ASCT) and gender. Further analyses of the result and their potential implications are ongoing.

Safety endpoints were treatment duration, frequency and grade of adverse events, frequency of events leading to dose modifications, and time to dose modifications. The safety and tolerability of melflufen plus dexamethasone, were consistent with previous reports. Hematological treatment emergent adverse events were most common, and generally clinically manageable with dose modifications. Despite higher frequencies of grade 3 or 4 thrombocytopenia and neutropenia with melflufen compared to pomalidomide, the number of concurrent grade 3 or 4 bleeding with thrombocytopenia and infection events with neutropenia were low. Most patients continued therapy after dose reduction and few adverse events resulted in discontinuation of treatment.

The publication is available on: https://www.thelancet.com/journals/lanhae/article/PIIS2352-3026(21)00381-1/fulltext

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About Oncopeptides

Oncopeptides is a biotech company focused on research and development of 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® (INN melphalan flufenamide), also called melflufen was granted accelerated approval in the U.S., on February 26, 2021, in combination with dexamethasone, for 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. Oncopeptides voluntarily withdrew the drug from the U.S. market on October 22, 2021, due to worse overall survival data in the phase 3 OCEAN study. The study was a post-approval requirement under the accelerated approval program. Oncopeptides is developing several new compounds based on the PDC platform. The Corporate Headquarters is based in Stockholm, Sweden. 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.