**Stockholm, Sweden** **Press release July 28, 2021**

## Regulatory update from US Food and Drug Administration

STOCKHOLM — July 28, 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 the US Food and Drug Administration, FDA, has issued a safety alert to patients and health care professionals, regarding an increased risk of death associated with Pepaxto® (melphalan flufenamide), in the OCEAN study.

https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-about-clinical-trial-results-showing-increased

Patient safety is paramount to Oncopeptides. The Company has an ongoing dialogue with the FDA and will provide updated information as soon as more information becomes available. The Company plans to submit complete data from the OCEAN-study to the International Myeloma Workshop meeting in Vienna on September 8-11, 2021.

### For more information, please contact:

Rolf Gulliksen, Global Head of Corporate Communications, Oncopeptides AB (publ)
E-mail: rolf.gulliksen@oncopeptides.com
Cell phone: + 46 70 262 96 28

Linda Holmström, Director of Investor Relations, Oncopeptides AB (publ)
E-mail: linda.holmstrom@oncopeptides.com
Cell phone: +46 70 873 40 95

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 persons above, on July 28, 2021, at 16:30 (CET).

### 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 superiority of Progression Free Survival as measured by 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. Recruitment of new patients to all clinical trials has been temporarily halted by the FDA pending further analyzes.

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.