

## Regulatory update from US Food and Drug Administration

STOCKHOLM — September 2, 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 announced a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee, on October 28, 2021 concerning Oncopeptides' product Pepaxto. The information is in line with the FDA safety alert on July 28, where the FDA stated that a public meeting may be held to discuss the safety findings from the OCEAN study.

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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 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<sup>®</sup> (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](http://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<sup>®</sup> (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.