Stockholm, Sweden **Press release December 07, 2022**

Oncopeptides provides update on Pepaxto US marketing authorization

STOCKHOLM — December 07, 2022 — 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 requested a withdrawal of the US marketing authorization for Pepaxto® (melphalan flufenamide, also called melflufen). The request is based on the outcome of the confirmatory phase 3 OCEAN study, which demonstrated an ITT overall survival HR of 1.1, but with significant survival result differences for both melflufen and the comparator drug pomalidomide for large relevant patient groups.

"We respect FDA´s accelerated approval regulations," says Jakob Lindberg, CEO of Oncopeptides. "Multiple myeloma remains an incurable disease, and the treatment options for patients with triple class refractory disease will ultimately become exhausted. The OCEAN study demonstrated clinical benefit for multiple myeloma patients, in particular for non-transplanted elderly patients where the unmet medical need remains very high."

Pepaxto was granted accelerated approval in the U.S., on February 26, 2021, and 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. At the FDA's request, Oncopeptides stopped marketing Pepaxto in the US on October 22, 2021, and Pepaxto is currently not commercially available for US patients.

The commercialization of Pepaxti® in Europe is ongoing. Pepaxti has a full approval from the European Medicines Agency, EMA, since August 18, 2022, and was approved by the Medicines and Healthcare Products Regulatory Agency, MHRA, in the UK on November 11, 2022. Both approvals take the large OCEAN study overall survival differences across relevant patient groups into account. Pepaxti is indicated in combination with dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapies, whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation.

The Company is developing its preclinical pipeline, including the next generation of drug candidates from the PDC platform, as well as an NK-cell engager, built on the technology platform of "Small Polypeptide based Killer Engagers", SPiKEs.

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

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 December 07, 2022, at 13:45 (CET).

About Oncopeptides

Oncopeptides is a global biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary Peptide Drug Candidate platform, PDC, to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. Pepaxti® (melphalan flufenamide, also called melflufen) has been granted Marketing Authorization, in the European Union, the EEA-countries Iceland, Lichtenstein and Norway, as well as the UK. Pepaxti is indicated in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapies, whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation.
Melflufen has been granted accelerated approval in the US under the trade name Pepaxto®. The product is currently not marketed in the US, due to regulatory hurdles.

Oncopeptides is developing several new compounds based on its proprietary technology platforms. The company is built on a Swedish innovation and is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. More information is available on www.oncopeptides.com.