Stockholm, Sweden **Press release September 23, 2022**

Oncopeptides provides an update from the meeting with FDAs advisory committee ODAC

STOCKHOLM — September 23, 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 Oncologic Drugs Advisory Committee (ODAC), of the US Food and Drug Administration (FDA), has finalized the discussion on the benefit-risk profile of Pepaxto® (melphalan flufenamide, also called melflufen). A majority of the panel considered that OCEAN did not confirm a favorable benefit-risk profile in the current indicated patient population. Pepaxto is indicated in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM), 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.

In the light of the outcome of the OCEAN trial, the FDA has asked the ODAC panel to vote on the following question: "Given the potential detriment in overall survival (OS), failure to demonstrate a progression-free survival (PFS) benefit, and lack of an appropriate dose, is the benefit risk profile of melphalan flufenamide favorable for the currently indicated patient population?" In a 14 to 2 vote, the ODAC answered no to the question.

"We still have confidence in our science and data. The heart of the ODAC discussion was focused on the highly heterogenous survival result in OCEAN across patient groups and how to interpret the subgroup data considering the ITT OS result," says Jakob Lindberg, CEO of Oncopeptides. "One day I believe that OCEAN may be recognized as the canary in the coal mine for immunomodulatory drugs that in our view is the main cause behind the OS heterogeneity and dissociation between PFS and OS in OCEAN and show that Pepaxto has the potential to become a meaningful treatment option for elderly patients with RRMM."

The FDA will not issue a final determination on the issues discussed until input from the advisory committee process has been considered and all reviews have been finalized.

Background material can be reached at https://www.fda.gov/media/161678/download.

Webcast for investors, analysts and media

Investors, analysts and media are invited to listen to a webcast presentation and participate in a following Q&A session on September 26, at 14:00 (CET). The event will be hosted by CEO Jakob Lindberg, accompanied by CMO Klaas Bakker. The presentation will be held in English.

Participant number:

SE: +46 856642651, **UK:** +44 3333000804, **US:** +1 6319131422

PIN for all numbers: 76812383#

Weblink:

https://tv.streamfabriken.com/pressconference-september-2022. The link can also be found on the Company's website.

For further information, please contact:

Rolf Gulliksen, Global Head of Corporate Communications, Oncopeptides AB (publ)
E-post: rolf.gulliksen@oncopeptides.com
Mobil: + 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 September 23, 2022, at 08:00 (CET).

About Oncopeptides and Pepaxto

Oncopeptides is a biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary PDC platform to develop peptide-drug conjugated 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 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. The Company voluntarily withdrew the drug on October 22, 2021, and then rescinded the withdrawal on January 21, 2022, based on comprehensive analyses of survival data from OCEAN and other relevant studies. Due to regulatory hurdles the product is currently not marketed in the U.S.

On August 18, 2022, the European Commission granted Pepaxti® (melphalan flufenamide) in combination with dexamethasone, marketing authorization in the European Union and countries in the European Economic Area, 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.

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