



Stockholm, Sweden

Briefing Book for ODAC meeting on benefit/risk profile of Pepaxto now published

STOCKHOLM — September 20, 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 US Food and Drug Administration (FDA), has published the Briefing Book for the Oncologic Drugs Advisory Committee (ODAC) meeting on September 22, 2022. The purpose of the meeting is to obtain the advisory committee's input regarding the benefit/risk of Pepaxto* (melphalan flufenamide, also called melflufen) for the currently indicated patient population.

"We have confidence in our science and data and look forward to discussing the results of the phase 3 OCEAN study during the ODAC meeting, which contribute important and unexpected learnings about Pepaxto, pomalidomide, and the immunomodulatory drug class (IMiDs)," says Jakob Lindberg, CEO of Oncopeptides. "EMA assessed the OCEAN study as a study that met its primary endpoint of superior PFS with true heterogeneity of survival benefit across relevant patient populations. That is in line with the scientific conclusions and position from Oncopeptides with relevant learnings from the heterogenous OCEAN survival result guiding future treatment and development."

"Oncopeptides is committed to enhancing treatment success in patients with RRMM treated with Pepaxto," says Klaas Bakker, MD, PhD, Executive Vice President and Chief Medical Officer. "That is why we are proactively communicating that the use of Pepaxto should be limited to only patients without prior autologous stem cell transplant or patients with post-ASCT progression more than 36 months after transplant regardless of the outcome of the ODAC meeting. "

The briefing book contains background information prepared by the FDA and Oncopeptides for the panel members of the ODAC. 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. This may be affected by issues not discussed at the ODAC meeting.

Background material can be reached at https://www.fda.gov/media/161678/download. The link to the live webcast will be published on www.oncopeptides.com.

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The information in the press release was submitted for publication, through the agency of the contact person above, on September 20, 2022, at 15:45 (CET).

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 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 treatment of adult patients with relapsed or refractory multiple myeloma. The Company voluntarily withdrew the drug on October 22, 2021, and then rescinded the withdrawal on January 21, 2022, based on comprehensive analyses of additional data. 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, for the treatment of adult patients with triple class refractory multiple myeloma. 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.