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Press release July 20, 2022

FDA announces an Oncologic Drugs Advisory Committee meeting to discuss benefit/risk profile of Oncopeptides' Pepaxto

STOCKHOLM — July 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 announced a forthcoming public advisory meeting of the Oncologic Drugs Advisory Committee (ODAC), on September 22, 2022, to discuss the benefit/risk of Pepaxto[®] (melphalan flufenamide).

On January 21 Oncopeptides announced that it has rescinded the October 22, 2021, letter requesting a voluntary withdrawal of the New Drug Application (NDA) of Pepaxto in the US. The decision was based on comprehensive analyses of the heterogenous overall survival data from the phase 3 OCEAN study, a head-to-head comparison with pomalidomide, as well as other relevant clinical trials. Oncopeptides initiated a dialogue with the FDA to review the data. The FDA interaction has been intensified following the recent European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) unanimous adoption of a positive opinion recommending the European Commission to grant a full marketing authorization approval of Pepaxti[®] (melphalan flufenamide) in the European Union (EU).

“This is a positive turn of events, and we are pleased to get the opportunity to share our data on the benefit/risk of Pepaxto with the ODAC and the public” says Klaas Bakker, MD, PhD, Executive Vice President and Chief Medical Officer. “Similarly, to the EMA Scientific Advisory Group (SAG) meeting in May, we intend to share comprehensive data confirming the true heterogeneity of the overall survival result of OCEAN”.

The purpose of the now scheduled ODAC meeting is to discuss the general benefit/risk profile of Pepaxto. In 2021, the purpose of the planned ODAC meeting was to have a discussion on next steps for Pepaxto including whether the indication should remain on the market while additional trial(s) are conducted. Consequently, the objective of this meeting is different than the planned ODAC in 2021.

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About Oncopeptides

Oncopeptides is a biotech company focused on research and development of pharmaceuticals for difficult-to-treat haematological 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[®] (melphalan flufenamide), 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. Due to regulatory hurdles the product is currently not marketed in the U.S. On June 23, 2022, the CHMP adopted a positive opinion recommending full approval of Oncopeptides Pepaxti[®] (melphalan flufenamide), in the EU in patients with triple class refractory multiple myeloma. Oncopeptides is developing several new compounds based on the PDC platform. The company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. More information is available on www.oncopeptides.com.