

Oncopeptides rescinds voluntary withdrawal of Pepaxto in the US – no intent to market in the US at this time

STOCKHOLM — January 21, 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hematological diseases, today announces that the Company has contacted the US Food and Drug Administration and rescinded the October 22, 2021, letter requesting voluntary withdrawal of the NDA of Pepaxto® (INN melphalan flufenamide, also called melflufen) in the US.

Further review and analyses of the heterogenous Overall Survival data from the phase 3 OCEAN study and other relevant trials have led the Company to reconsider its previous voluntary withdrawal request. Oncopeptides has discontinued the marketing of Pepaxto in the US and does not intend to market Pepaxto in the US at this time. The company has initiated a dialogue with the FDA to review the new data.

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 persons below, on January 21, 2022, at 21:20 (CET).

Conference call for investors, analysts and the media

Investors, financial analysts and media are invited to participate in a webcast with a Q&A session on January 24, 2022, at 09:00 (CET). The event will be hosted by CEO, Jakob Lindberg and CMO, Klaas Bakker.

Webcast

The webcast will be streamed via <https://tv.streamfabriken.com/press-conference-jan-2022>

The link can also be found on the website: www.oncopeptides.com.

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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 peptide-drug conjugate (PDC) platform to develop 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 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. Oncopeptides voluntarily stopped marketing the drug on the U.S. market on October 22, 2021. The study was a post-approval requirement under the accelerated approval program. Oncopeptides is developing several new compounds based on the PDC platform. The Corporate Headquarters is based in Stockholm, Sweden. The company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. More information about the company is available on www.oncopeptides.com.