Stockholm, Sweden **Press release October 22, 2021**

Oncopeptides withdraws Pepaxto® in US, scale down organization and focus on R&D

STOCKHOLM — October 22, 2021 — 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 company has decided to withdraw Pepaxto® (INN melphalan flufenamide) from the market in the US, following the phase 3 OCEAN study, which showed an overall survival in the ITT population with a HR of 1.104. The decision has been made after interactions and dialogue with the US Food and Drug Administration, FDA. Pepaxto was granted accelerated approval on February 26th 2021.

During our dialogue with FDA it has become evident that the FDA does not consider that the phase 3 OCEAN study meets the criteria of a confirmatory study. Oncopeptides believes that the OCEAN data are scientifically meaningful and that the findings warrant further evaluation.

As a consequence Oncopeptides will immediately refocus the company and return to being a Sweden based R&D company, dedicated to further develop our proprietary Peptide Drug Conjugate (PDC) platform including the next generation of drug candidates including OPD5 and OPDC3. The organization will be scaled down to increase our cash runway and focus on building a platform for longer term development and growth. The commercial business units in the US and Europe will be closed down and the Stockholm based organization will be significantly reduced.

The application to the European Medicines Agency, EMA, for a potential Conditional Marketing Authorization of melflufen (melphalan flufenamide) in the EU, based on the pivotal phase 2 HORIZON study in relapsed refractory multiple myeloma, remains pending. The company expects to receive a CHMP opinion in Q2, 2022.

“The decision to withdraw Pepaxto from the market has been a difficult decision, that has been made with great consideration and with the best intentions for patients and shareholders," says Marty J Duvall, Chief Executive Officer at Oncopeptides. “The Company now needs to refocus its resources and energy on R&D and remain true to its mission of bringing hope to patients through science. We believe that this is the only viable path forward to accomplish this goal.”

“We remain confident in our scientific platform, despite the fact that the OCEAN data didn´t pass the regulatory hurdle to confirm the accelerated approval in the US,” says Jakob Lindberg, CSO at Oncopeptides. “Going forward we will further explore our PDC-platform, to develop drugs that potentially can make a significant difference for patients. Oncopeptides is committed to work closely with the regulatory authorities to evaluate the most appropriate possibilities for our pipeline products.”

Oncopeptides will work together with the FDA to continue to make the drug available for patients currently treated with Pepaxto.

Based on the above news Oncopetides has decided to postpone the Q3 report until November 24.

For more information, please contact:

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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 October 22, 2021, at 14:55 (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 at 16:30 (CET). The event will be hosted by CEO, Marty J Duvall, CMO, Klaas Bakker and CSO Jakob Lindberg.

Weblink

The webcast will be streamed via https://tv.streamfabriken.com/oncopeptides-oct-2021
The link can also be found on the website: www.oncopeptides.com.

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About Oncopeptides

Oncopeptides is a global biotech company focused on the development of targeted 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® (melphalan flufenamide) 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. Pepaxto was withdrawn from the market on October 22, 2021, due to a overall survival data in the ITT population of the phase 3 OCEAN study, with a HR of 1.104. Oncopeptides is developing several new compounds based on the PDC platform. The global Headquarters is based in Stockholm, Sweden and the U.S. Headquarters is situated in Boston, Massachusetts. 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.