

Update on the Type II application process

Stockholm – December 15, 2023 – Oncopeptides today announces that the European Commission has decided to formally approve the company's application to the European Medicines Agency (EMA) for an extended indication for Pepaxti into earlier lines. The previously communicated decision by Oncopeptides to opt out of the process to extend the indication remains.

Oncopeptides has submitted an application to adjust the indication of Pepaxti to the originally approved indication, a process that is expected to be finalized in early 2024. During this time, Oncopeptides will work together with the European Commission, EMA as well as local stakeholders to ensure an efficient removal process for the extended indication.

For more information, including a Q&A for investors, please visit [Oncopeptides' website](#).

For more information, please contact:

David Augustsson, Director of Corporate Affairs, Oncopeptides AB (publ)

E-mail: david.augustsson@oncopeptides.com

Cell phone: +46 76 229 38 68

About Oncopeptides

Oncopeptides is a biotech company focused on research, development, and commercialization of therapies for difficult-to-treat hematological diseases. The company uses its proprietary Peptide Drug Candidate platform (PDC) to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells.

Pepaxti® (melphalan flufenamide, also called melflufen) has been granted Marketing Authorization, in the European Union, the EEA-countries Iceland, Lichtenstein and Norway, as well as in the UK. Pepaxti is indicated 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. Melflufen has been granted accelerated approval in the US under the trade name Pepaxto®. The drug is currently not marketed in the US.

Oncopeptides is developing several new compounds based on its proprietary technology platforms and is listed on the Small Cap segment on Nasdaq Stockholm with the ticker ONCO. For more information see: www.oncopeptides.com.

Attachments

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