Press Release
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Information regarding Oncopeptides' appeal of U.S. withdrawal published

Stockholm – August 25, 2023 – Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces that more information regarding the formal request from the U.S. Food and Drug Administration (FDA) to voluntarily withdraw Pepaxto ´s approval in the U.S has been made available by the FDA.

The public docket contains, among other documents, a detailed appeal document outlining Oncopeptides ´ arguments for why Pepaxto should remain on the U.S. market as an important treatment option for multiple myeloma patients in later lines of treatment.

"Our OCEAN study demonstrated clinical benefit for multiple myeloma patients, in particular for non-transplanted elderly patients where the unmet medical need remains very high, and we remain confident that it would provide value for patients all over the world, including the U.S.," says Sofia Heigis, CEO of Oncopeptides. "We value the opportunity to share our perspective and look forward to a continued dialogue with the FDA."

Please visit Oncopeptides' website for additional information, including a Q&A for investors.

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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