Press Release
28 September 2023 11:15:00 CEST

Oncopeptides opts to abandon Type II variation process for Pepaxti to optimize patient and shareholder value

Stockholm – September 28, 2023 – Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces its decision to opt to abandon the application process to allow Pepaxti access to earlier lines of treatment for patients with relapsed, refractory multiple myeloma (RRMM), a so-called type II variation. The decision follows an updated, comprehensive analysis of the current landscape for treatment of multiple myeloma and is made to optimize value for both patients and shareholders. The decision does not impact the company´s financial projections or the estimated market potential of Pepaxti negatively.

In its analysis, Oncopeptides has concluded that the highest value for both patients and shareholders lies in the current indication, due to a high unmet medical need, a fair price reflecting the innovation of Pepaxti and fewer alternative treatments.

The company assesses that this decision does not negatively affect the previously communicated market potential for Pepaxti in Europe (i.e. >1.5 billion SEK), or when the company can expect to be cash flow positive (i. e. before end of 2026).

“While we have strong scientific support and are pleased with the clinical benefit/risk profile, confirmed by the recent positive opinion from the CHMP, our assessment is that we would serve patients best if the drug remained within its current indication where the unmet medical need remains high and the number of patients is increasing,” says Sofia Heigis, CEO of Oncopeptides. “The European treatment landscape already holds a broad range of viable options with a mix of both generic and innovative drugs. To move forward with an extension into earlier lines of treatment before fulfilling the higher unmet need in later lines could mean a new European price level for Pepaxti that does not reflect our innovation and ultimately risk the availability of Pepaxti for all patients and also erode shareholder value. We are convinced that focusing on later lines of treatment in a growing market is in the best interest of both patients and our shareholders.”

For more information, please visit Oncopeptides’ website where a Q&A for investors as well as a video interview where Sofia Heigis further describes the decision, will be published shortly.

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This information 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 set out above, at 2023-09-28 11:15 CEST.

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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