Press Release
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Oncopeptides' Pepaxti formally approved for full reimbursement in Italy

Stockholm, January 27, 2025 – Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces that the positive reimbursement decision for its drug Pepaxti (melflufen) has been published in the Italian Official Journal ("IOJ", It.: Gazetta Ufficiale). This marks the final regulatory step for the drug's upcoming commercialization in Italy, confirming Oncopeptides' expectation of first sales during H1, 2025.

With the IOJ publication, Oncopeptides can now initiate the regional access process to bring Pepaxti to patients. The company's goal is to make the treatment available to eligible Italian patients with relapsed and refractory multiple myeloma over the coming months.

"We are now ready to start making Pepaxti accessible to patients who urgently need new and innovative treatment options, and we expect to commence launch activities during the first quarter," said **Bruno Bolognese, Country Manager Italy and European Head of Medical Affairs at Oncopeptides**. "Italy represents a key market for Oncopeptides, with its large patient population and extensive clinical experience with Pepaxti."

Italy reports an annual incidence of approximately 6,000 new cases of multiple myeloma, and with about 1,800 patients falling within Pepaxti's target population. 79 patients across 10 Italian hospitals during the clinical development of Pepaxti and 86 treated patients in the Early Access Program (EAP) underscores the clinical experience in the country and high unmet need for the drug. The Early Access program have been closed following the reimbursement.

As previously communicated, Oncopeptides is currently in the process of strengthening its presence in Italy by expanding its team and investing in initiatives to raise awareness about Pepaxti and its benefits.

For more information, please visit www.oncopeptides.com

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About Oncopeptides

Oncopeptides is a biotech company focusing on research, development and commercialization of targeted therapies for difficult-to-treat cancers. 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.

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

Attachments

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