

Oncopeptides obtains reimbursement for Pepaxti in Italy

Stockholm, November 27, 2024 – Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces that it has come to an agreement with the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) on the pricing and reimbursement of melflufen, branded in Europe as Pepaxti. The decision paves the way for the drug to be commercialized in Italy during H1, 2025.

The agreement with AIFA's and its Scientific Pricing and Reimbursement Committee (CSE) on market access for Pepaxti at a price that reflects the innovation of Pepaxti and is in line with the financial projections of the company paves the way for Oncopeptides to move forward with the regional access process. The company's ambition is for Pepaxti to become available to patients during the first half of 2025.

The Italian market is expected to become one of Oncopeptides most important European markets with a yearly incidence of about 6,000 multiple myeloma patients, of which about 1,800 are within Pepaxti's target population. Oncopeptides is currently conducting an Early Access Program in Italy which has included 83 patients over time emphasizing the unmet need for Pepaxti in Italy.

"With its large patient population and broad clinical experience from Pepaxti, Italy is a key market for Oncopeptides. This is great news for Italian patients suffering from relapsing, refractory multiple myeloma as well as a major step forward for our company's ambition to reach profitability by the end of 2026", said Sofia Heigis, CEO of Oncopeptides.

Following the agreement with AIFA, Oncopeptides will continue strengthening its presence in Italy during the regional access phase.

"Me and the team are grateful for the support we have received by the myeloma community in Italy and in the next few weeks and months we will more than double our Italian team and invest in awareness and other premarketing activities to ensure that we build onto the already strong momentum we see in the country," said Bruno Bolognese, Country Manager, Italy at Oncopeptides.

For more information, please visit [Oncopeptides.com](https://oncopeptides.com)

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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 2024-11-27 13:49 CET.

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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