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Oncopeptides submits application for conditional marketing authorization of melflufen in the EU

STOCKHOLM — April 16, 2021 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a global biotech company focused on the development of therapies for difficult-to-treat hematological diseases, today announces that the Company has submitted an application to the European Medicines Agency, EMA, for conditional marketing authorization of melflufen (melphalan flufenamide) in the EU, based on the pivotal phase 2 HORIZON study in relapsed refractory multiple myeloma. Pending a positive validation from the EMA, melflufen will be subject to a regulatory assessment according to the standard timelines.

"Following Oncopeptides´ launch in the US, we are broadening our geographical footprint and submitting an application for conditional marketing authorization of melflufen in Europe ahead of expectations", says Marty J Duvall, Chief Executive Officer at Oncopeptides. "This major milestone marks the commitment of our organization to bring hope to multiple myeloma patients around the world, through innovative science".

"This is vitally important and supports the development of a dedicated organization across Europe", says Andrea Passalacqua, General Manager Europe, Oncopeptides. "We believe that melflufen may address a growing medical need in patients with relapsed refractory multiple myeloma in Europe. In order to help accomplishing this, we have also introduced an Early Access Program that offers eligible patients access to melflufen ahead of a potential marketing authorization".

According to the European Medicines Agency, medicines are eligible for conditional approval if they are aimed at treating or preventing seriously debilitating or life-threatening diseases. Conditional marketing authorizations may be granted if the benefit-risk balance of the product is positive, comprehensive data can be provided, there is an unmet medical need, and the benefit to public health of making the product available outweighs the risks due to need for additional data.

On February 26th the U.S. Food and Drug Administration, FDA, approved PEPAXTO® (melphalan flufenamide), in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.

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About Oncopeptides

Oncopeptides is a global biotech company focused on the development of targeted therapies for difficult-to-treat hematological diseases. The company uses its proprietary peptide-drug conjugate (PDC) platform to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. The first drug stemming from the PDC platform, PEPAXTO® (melphalan flufenamide), has been launched in the U.S., for the treatment of adult patients with relapsed or refractory multiple myeloma. Melphalan flufenamide is evaluated in a comprehensive clinical study program including the global phase 3 studies OCEAN and LIGHTHOUSE. Oncopeptides is developing several new compounds which are based on the PDC platform. The first one is expected to enter into clinical development in 2021.

Oncopeptides has approximately 300 coworkers. The global Headquarters is based in Stockholm, Sweden and the U.S. Headquarters is situated in Boston, Mass. The company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO. More information is available on www.oncopeptides.com.

About melphalan flufenamide

Melphalan flufenamide, also known as melflufen, is a first-in-class peptide-drug conjugate that targets aminopeptidases and rapidly releases alkylating agents inside cancer cells. Aminopeptidases are overexpressed in multiple myeloma cells and are associated with advanced disease and tumor mutational burden. Targeting aminopeptidases causes selective activity in cancer cells, sparing healthy cells.

In the US, PEPAXTO® (melphalan flufenamide) is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.