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Oncopeptides strengthens leadership in Europe and opens an Early Access Program in multiple myeloma

STOCKHOLM — March 8, 2021 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a global biotech company focused on the development of therapies for difficult-to-treat hematological diseases, today announced that it strengthens the leadership of the European operations by appointing Andrea Passalacqua as General Manager in Europe, and Pamela Bacon as Head of Medical Affairs Europe. The Company also announced that it opens an Early Access Program across Europe to address the significant need of new treatment alternatives in multiple myeloma. As previously announced, Oncopeptides will also seek a Conditional Marketing Authorization of melphalan flufenamide in triple class refractory multiple myeloma, during second quarter of 2021.

"I am excited that we are able to expand our footprint in Europe shortly after the launch of PEPAXTO®, melphalan flufenamide, in the US,", says Marty J Duvall, Chief Executive Officer at Oncopeptides AB. "This demonstrates our dedication to provide patients with difficult-to-treat hematological diseases, access to new and innovative treatment options".

In his capacity as General Manager in Europe, Andrea Passalacqua will be part of the global Leadership Team of Oncopeptides AB. Andreas brings extensive commercial experience from Amgen and Celgene in multiple myeloma, and most recently he served as General Manager in Italy for Bluebird Bio. Pamela Bacon carries a significant proficiency in the multiple myeloma space and has an in-depth experience from several global Medical Affairs roles within Celgene and Amgen.

"I am looking forward to contributing to the continued success of Oncopeptides by building and leading a dedicated commercial organization in Europe", says Andrea Passalacqua, General Manager in Europe, at Oncopeptides. "Melphalan flufenamide has the potential to address a growing medical need in relapsed or refractory multiple myeloma and thus bringing significant clinical value and hope to myeloma patients".

"This is a very exciting time to join Oncopeptides", says Pamela Bacon, Head of Medical Affairs in Europe. "During the recent years Oncopeptides has executed a comprehensive clinical program in multiple myeloma. It´s my ambition to further anchor this with Key Opinion Leaders and prepare the ground for a Conditional Marketing Authorization in Europe".

The submission of melphalan flufenamide in combination with dexamethasone in patients with triple class refractory multiple myeloma, to the European Medicines Agency, will be built on the HORIZON data, which also formed the basis for the NDA-submission to FDA for accelerated approval in the US. The complete results from the HORIZON study were published in the Journal of Clinical Oncology in December 2020.

On the back of a well-received Expanded Access Program in the US, Oncopeptides intends to roll out an Early Access Program in Europe. Physicians may apply for melphalan flufenamide treatment for patients who cannot be adequately treated with approved and commercially available medications, or drugs that are available through clinical trials.

To be eligible for treatment in the program patients must have relapsed or refractory multiple myeloma, received at least two prior lines of therapy and be refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody (i.e. be triple class refractory).

"I am very pleased that we will be able to provide patients across Europe, who currently have no or very limited treatment options, early access to melphalan flufenamide", says Sofia Heigis, Global Head of Medical Affairs. "Patients with multiple myeloma have a significant medical need, that has been confirmed by requests from healthcare providers and external experts across Europe".

These organizational changes are important steps in the development of Oncopeptides AB into a fully-fledged commercial biotech company. Going forward the geographic business leaders will report directly to the CEO in an organizational structure designed to prioritize the relationship with our customers. In conjunction with these changes, Paula Boultbee, Chief Commercial Officer since 2016, has decided to retire after 30 years in leading oncology marketing roles. Paula played an instrumental role early in the company's commercial evolution, helping to establish Oncopeptides Inc. and paving the way for the launch of PEPAXTO (melphalan flufenamide) in the US and potentially other geographies.

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About Multiple Myeloma

Multiple myeloma is a cancer that impacts plasma cells, a type of white blood cell which produces antibodies to help fight infection. Multiple myeloma causes cancer cells to accumulate in the bone marrow. Approximately 7 per 100,000 Americans are each year diagnosed with multiple myeloma, making it a rare disease. A growing subset of this population is becoming triple-class refractory. This means that their disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. The number of patients diagnosed with multiple myeloma is growing and the number of cases diagnosed annually is expected to almost double in 20 years. The average age for diagnosis is 70 years, and there is currently no cure.

About the HORIZON Study

In total, 157 multiple myeloma patients have been enrolled in the pivotal phase 2 HORIZON study, evaluating intravenous melflufen in combination with dexamethasone. The approval of melphalan flufenamide, also known as melflufen, was based on a subgroup of HORIZON patients (n=97) that were refractory to at least one treatment

in each of the three standard-of-care classes: proteasome inhibitor, immunomodulatory agent, and CD38-directed monoclonal antibody and had received at least four prior lines of treatment. In this subset of patients, the Overall Response Rate (ORR) was 23.7% and Median Duration of Response (DOR) was 4.2 months. The most frequent adverse reactions (≥10%; Grade 1-4) were fatigue (55%), nausea (32%), diarrhea (27%), pyrexia (24%), and respiratory tract infection (24%). The most common laboratory abnormalities (Grade 1-4) were leukocytes decrease (99%), platelets decrease (99%), lymphocytes decrease (97%), neutrophils decrease (95%), hemoglobin decrease (84%), and creatinine increase (68%).

About melphalan flufenamide

Melphalan flufenamide, also known as melflufen, is the first anticancer peptide-drug conjugate for patients with relapsed or refractory multiple myeloma. Melphalan flufenamide uses innovative technology that links a peptide carrier to a cytotoxic agent, resulting in a lipophilic compound. Due to its lipophilicity, melphalan flufenamide is distributed into cells. Melphalan flufenamide is designed to leverage aminopeptidases, which are overexpressed in multiple myeloma cells and cause the release of cytotoxic agents. Melphalan flufenamide is administered once monthly, by a thirty-minute infusion.

In the US, PEPAXTO® (melphalan flufenamide) is indicated in combination with dexamethasone for the treatment of adult patients with triple class 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-monoclonal directed antibody. PEPAXTO® is a registered trademark in the U.S.

About Oncopeptides

Oncopeptides is a global biotech company focused on the development of targeted therapies for difficult-to-treat hematological diseases. The Company has recently been granted accelerated approval by the U.S. FDA for PEPAXTO (melphalan flufenamide, also known as melflufen), in relapsed or refractory multiple myeloma. Melphalan flufenamide is the first drug originated from the Company´s proprietary PDC-platform and is evaluated in a comprehensive clinical study program, including the ongoing phase 3 OCEAN study. Melphalan flufenamide is the first anticancer peptide-drug conjugate for patients with relapsed or refractory multiple myeloma. The product uses innovative technology that links a peptide carrier to a cytotoxic agent, resulting in a lipophilic compound. Due to its lipophilicity, it is distributed into cells. Melphalan flufenamide is designed to leverage aminopeptidases, which are overexpressed in multiple myeloma cells and cause the release of the cytotoxic agents. Oncopeptides' global Headquarters is 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.