

Oncopeptides presents new clinical and preclinical melflufen data at the upcoming European Hematology Association meeting

STOCKHOLM — May 12, 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 new clinical and preclinical data have been accepted by the European Hematology Association, EHA, and been published online. The clinical data presentation contains interim results from the phase 2 BRIDGE study supporting the use of melflufen in relapsed refractory multiple myeloma patients with moderately impaired renal function. Two preclinical data presentations show the future potential of melflufen in treatments of other hematological diseases outside multiple myeloma. In addition, the last preclinical data presentation provides an increased understanding of melflufen 's mode of action.

“The phase 2 BRIDGE study supports the use of melflufen in relapsed refractory multiple myeloma patients with renal impairment, which comprises a significant number of multiple myeloma patients” says Klaas Bakker, MD, PhD, Executive Vice President and Chief Medical Officer at Oncopeptides. “In addition, our strong proprietary PDC platform makes us uniquely positioned to become a major player in other hematological malignancies. Based on preclinical data presented here at EHA we have broadened our clinical development program outside multiple myeloma to include relapsed Acute Myeloid Leukemia (AML) and relapsed Diffuse Large B-Cell Lymphoma (DLBCL), two indications with a particular high unmet medical need.”

Below is a brief description of the abstracts that have been accepted by the EHA. They will be available online at ehaweb.org, from May 12th at 16:00 (CET).

1. BRIDGE (OP-107): A PHASE 2 PHARMACOKINETIC STUDY OF MELFLUFEN PLUS DEXAMETHASONE IN PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA AND IMPAIRED RENAL FUNCTION

The study demonstrates that for patients receiving melflufen in the phase 2 BRIDGE study, the exposure to melphalan increased with reduced eGFR (Estimated Glomerular Filtration Rate), similar to what is observed during treatment with melphalan. The overall toxicity profile was as expected for melflufen and dexamethasone and no new safety signals were observed, supporting the use of melflufen in patients with moderate renal impairment.

2. MELFLUFEN DEMONSTRATES HIGH EFFICACY IN CYTARABINE AND VENETOCLAX RESISTANT AML MODELS

The study shows that multiple aminopeptidases are highly expressed in AML-samples, providing a good rationale for using melflufen therapy. Patients with Acute Myeloid Leukemia, often develop resistance to current treatments, including cytarabine and venetoclax, yet in pre-clinical models of resistance to these agents, melflufen shows high efficacy.

3. MELPHALAN FLUFENAMIDE IS A HIGHLY POTENT ANTI-NEOPLASTIC AGENT IN HIGH RISK DLBCL MODELS

Several aminopeptidase genes are highly expressed in samples of patients with DLBCL, Diffuse Large B-Cell Lymphoma, and their elevated expression is associated with significantly shorter survival. In preclinical in vitro tests of DLBCL cell lines, melflufen shows superior cytotoxicity compared to Standard of Care drugs doxorubicin and bendamustine.

4. MELFLUFEN RAPIDLY ACCUMULATES WITHIN TUMOR CELLS AND DISTRIBUTES AN ALKYLATING PAYLOAD TO THE NUCLEUS AND MITOCHONDRIA

The increased lipophilicity of melflufen can affect the redistribution of the alkylating payload within the cell. Data show that melflufen, but not melphalan, localized significantly within lysosomes, endoplasmic reticulum and importantly mitochondria, which may affect the mechanism of cancer cell killing.

PEPAXTO[®] (melphalan flufenamide, also known as melflufen), in combination with dexamethasone, was granted accelerated approval by the FDA on February 26, 2021, 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.

For more information, please contact:

Rolf Gulliksen, Global Head of Corporate Communications, Oncopeptides AB (publ)

E-mail: rolf.gulliksen@oncopeptides.com

Cell phone: + 46 70 262 96 28

Linda Holmström, Director of Investor Relations, Oncopeptides AB (publ)

E-mail: linda.holmstrom@oncopeptides.com

Cell phone: +46 70 873 40 95

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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.

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 coming from 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 based on the PDC platform. In 2021 the second compound from the PDC platform, OPD5, is expected to enter clinical development.

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.