

Oncopeptides Announces that New Data for Melflufen is Accepted for Presentation at the Annual American Society of Hematology Meeting

STOCKHOLM — November 4, 2020 — Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a pharmaceutical company focusing on the development of targeted therapies for difficult-to-treat hematological diseases, today announced that twelve abstracts, including one oral presentation, have been accepted for the upcoming virtual American Society of Hematology (ASH) meeting on December 5-8, 2020. Key clinical abstracts focus on data from the ongoing phase 1/2 ANCHOR combination study and the pivotal phase 2 HORIZON study. The preclinical abstracts further explore the mechanism of action of the proprietary peptide-drug conjugate platform in multidrug resistant models of multiple myeloma. The abstracts are published online today at <https://www.hematology.org/meetings/annual-meeting/abstracts>.

The updated analysis of the ongoing phase 1/2 ANCHOR study confirms the initial findings of encouraging activity as a triplet regimen with melflufen plus dexamethasone and either daratumumab or bortezomib in patients with relapsed refractory multiple myeloma and sets the foundation for the planned phase 3 LIGHTHOUSE daratumumab combination study.

Seven clinical abstracts are based on the HORIZON study, most notable are the subgroup analysis of patients exposed to and refractory to alkylators and the analysis of patients with extramedullary disease, that further verify the distinct mechanism of action of melflufen.

“We look forward to sharing a robust dataset from our clinical and pre-clinical programs in multiple myeloma which further validates the strength of our peptide-drug conjugate platform,” says Klaas Bakker, MD, PhD, Chief Medical Officer of Oncopeptides. “These abstracts provide a comprehensive and multi-faceted analysis of the safety and efficacy of melflufen. Collectively, these results demonstrate our continued commitment to finding a novel therapeutic approach for heavily treated, high risk multiple myeloma patients, with a particularly poor prognosis and limited treatment options.”

Below is a brief description of the abstracts that have been accepted by the American Society of Hematology.

| Clinical abstracts | First Author | Abstract Code | Disposition |
|---|---------------------------|---------------|-------------|
| ANCHOR | | | |
| ANCHOR (OP-104): Melflufen Plus Dexamethasone (dex) and Daratumumab (dara) or Bortezomib (BTZ) in Relapsed/Refractory Multiple Myeloma (RRMM) Refractory to an IMiD and/or a Proteasome Inhibitor (PI)—Updated Efficacy and Safety. | Ocio E, et. al. | 417 | Oral |
| HORIZON | | | |
| HORIZON (OP-106): Melflufen Plus Dexamethasone (dex) in Patients (pts) with Relapsed/Refractory Multiple Myeloma (RRMM) Exposed to Prior Alkylator Therapy—Subgroup Analysis | Roudriguez-Otero P, et.al | 2321 | Poster |

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| HORIZON (OP-106): Melflufen Plus Dexamethasone (dex) in 55 Patients (pts) with Relapsed/Refractory Multiple Myeloma (RRMM) with Extramedullary Disease (EMD)—Subgroup Analysis. | Richardson, PG, et.al | 3214 | Poster |
| HORIZON (OP-106): Melflufen Plus Dexamethasone in Patients with Relapsed/Refractory Multiple Myeloma with High-Risk Cytogenetics—Subgroup Analysis. | Mateos MV, et.al | 3237 | Poster |
| HORIZON (OP-106): Melflufen Plus Dexamethasone in Patients with Relapsed/Refractory Multiple Myeloma—Age Subgroup Analysis of Elderly Patients. | Larocca A et.al. | 2293 | Poster |
| HORIZON (OP-106): Melflufen Plus Dexamethasone (dex) in Patients (Pts) with Relapsed/Refractory Multiple Myeloma (RRMM)—Health-related Quality of Life (HR QoL) Analysis. | Oriol A, et.al. | 3477 | Poster |
| HORIZON (OP-106): Melflufen Plus Dexamethasone (dex) in Patients (pts) with Relapsed/Refractory Multiple Myeloma (RRMM)—Analysis of Adverse Events Related to Hospitalizations. | Nadeem O, et.al. | 2564 | Poster |
| HORIZON (OP-106) Versus MAMMOTH: An Indirect Comparison of Efficacy Outcomes for Patients with Relapsed/Refractory Multiple Myeloma (RRMM) Refractory to Anti-CD38 Monoclonal Antibody Therapy Treated with Melflufen Plus Dexamethasone Versus Conventional Agents. | Blade J, et.al. | TBC | Publication only |
| Pre-clinical abstracts | | | |
| Effect of ABCB1 Multidrug Resistance Protein on Efficacy of Anti-Myeloma Drugs in Carfilzomib Resistant Myeloma Model. | Byrgazov K, et.al. | | Poster |
| Melflufen Shows Efficacy Against Bortezomib-Resistant Multiple Myeloma Models Including Myeloma Stem Cells | Byrgazov K, et.al. | | Poster |
| Anti-Myeloma Drug Melflufen Inhibits RANKL Osteoclastogenesis By Suppressing Proliferation of CD14+ Precursor Cells | Byrgazov K, et.al. | | Poster |
| Novel Alkylating Agent Melflufen Displays Potent Efficacy in Samples from Patients with High Risk Subsets of Multiple Myeloma Including Plasma Cell Leukemia | Idler B, et.al. | | Poster |

Melflufen (INN Melphalan flufenamide) is an investigational first-in-class peptide-drug conjugate (PDC) that targets aminopeptidases and rapidly releases alkylating agents into tumor cells. Melflufen is in late-stage clinical development for the treatment of patients with triple-class refractory multiple myeloma and has recently been granted a priority review by the U.S. Food and Drug Administration, FDA, for a New Drug Application based on the results from the phase 2 HORIZON study.

For more information, please contact:

Klaas Bakker, MD, PhD, Chief Medical Officer of Oncopeptides

E-mail: klaas.bakker@oncopeptides.com

Cell: +44 7818 523903

Rein Piir, Head of Investor Relations at Oncopeptides

E-mail: rein.piir@oncopeptides.com

Cell phone: +46 70 853 72 92

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About melflufen

Melflufen (INN melphalan flufenamide) is a first in class peptide-drug conjugate (PDC) that targets aminopeptidases and releases alkylating agents into tumor cells. Melflufen is rapidly taken up by myeloma cells due to its high lipophilicity and is immediately hydrolyzed by peptidases to release an entrapped hydrophilic alkylator payload. Aminopeptidases are overexpressed in tumor cells and are even more pronounced in advanced cancers and tumors with a high mutational burden. In vitro, melflufen is 50-fold more potent in myeloma cells than the alkylator payload itself due to the increased intracellular alkylator concentration. Melflufen displays cytotoxic activity against myeloma cell lines resistant to other treatments, including alkylators, and has also demonstrated inhibition of DNA repair induction and angiogenesis in preclinical studies. In the pivotal phase 2 HORIZON study melflufen plus dexamethasone demonstrated encouraging efficacy and a clinically manageable safety profile in heavily pretreated patients with relapsed refractory multiple myeloma, with primarily hematologic Adverse Events (AE) and a low incidence of non-hematologic AEs.

About Oncopeptides

Oncopeptides is a pharmaceutical company focused on the development of targeted therapies for difficult-to-treat hematological diseases. The lead product candidate melflufen, is a first in class peptide-drug conjugate that targets aminopeptidases and releases alkylating agents into tumor cells. Melflufen is in development as a new treatment for the hematological malignancy multiple myeloma and is being tested in multiple clinical studies including the pivotal phase 2 HORIZON study and the phase 3 OCEAN study. Based on the results from the HORIZON study a New Drug Application has been submitted to the U.S. Food and Drug Administration, FDA, for accelerated approval of melflufen in combination with dexamethasone for treatment of adult patients with triple-class refractory multiple myeloma. The FDA has granted the New Drug Application a priority review with a PDUFA date of February 28, 2021. 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.