



Stockholm, Sweden

Press release August 16, 2019

## **Oncopeptides Announces Acceptance of Data for Presentation at International Myeloma Workshop, September 12-15**

**Stockholm – August 16, 2019 - Oncopeptides AB (Nasdaq Stockholm: ONCO) announced today the acceptance of an oral late breaking presentation providing updated melflufen data from the Phase 2 pivotal OP-106 HORIZON study as well as two poster presentations at the 17<sup>th</sup> International Myeloma Workshop (IMW) meeting (September 12-15, Boston, Massachusetts, USA).**

**Melflufen is a lipophilic peptide-conjugated alkylator belonging to a novel class of Peptidase Enhanced Cytotoxics (PEnC) and is presently being evaluated in a broad global clinical development program.**

### **Comment from CEO Jakob Lindberg**

“We are looking forward to the upcoming IMW meeting. IMW is an important myeloma-specific meeting held every two years. Professor Paul G. Richardson will be presenting data from the phase 2 HORIZON study at the oral late breaking session on melflufen’s activity in patients with relapsed-refractory multiple myeloma (RRMM) and extra medullary disease (EMD). At the European Hematology Association (EHA) in June, interim data were presented suggesting that melflufen may be the first drug to exhibit meaningful activity in this difficult to treat EMD patient population. To our knowledge, HORIZON represents the largest clinical trial cohort of EMD patients to date and there is a clear unmet medical need in this rapidly growing patient population” said Jakob Lindberg, CEO Oncopeptides. “Melflufen, in combination with dexamethasone, demonstrates encouraging activity in advanced RRMM patients with EMD. Response rates appear higher than observed in prior studies and this could be linked to melflufen’s unique mechanism of action. These results are encouraging, and we continue to monitor this patient group in ongoing and future clinical trials”.

### **Upcoming presentations at IMW**

The HORIZON data will be presented as an oral presentation by Professor Paul G. Richardson, in the plenary session “Late Breaking Abstracts” on Sunday, September 15 at 08.30 AM (ET) (14.30 CET) under the title: Activity of Melflufen in RRMM Patients with Extramedullary Disease in the Phase 2 HORIZON Study (OP-106) – Promising Results in a High-Risk Population.

The first poster presentation will be held during Poster Session I, Multiple Myeloma Genomics – Friday, September 13 at 6.30 – 8.00 PM (ET) (Saturday, September 14 at 00.30 - 02.00 CET) under the title: Amino peptidase gene expression in myeloma.

The second poster presentation will be held during Poster Session II, Treatment of Previously Treated Myeloma – Saturday, September 14 at 12.30 – 2.00 PM (ET) (18.30 - 20.00 CET) under the title: Quality of life treatment for relapsed/refractory multiple myeloma, a systematic review.

Paul G. Richardson, MD, is Professor of Medicine at Harvard Medical School and Clinical Program Leader, Director of Clinical Research at the Jerome Lipper Multiple Myeloma Center Dana-Farber Cancer Institute in Boston, Massachusetts, USA.

### **About the OP-106 HORIZON study**

Patient recruitment in the pivotal HORIZON study is ongoing. The goal is to include 150 patients in the study with the last patient included during Q3 2019. The patients in the study are refractory to pomalidomide and/or daratumumab after failing on immunomodulatory drugs (IMiDs) and proteasome inhibitors (PIs). Interim data were presented at the EHA meeting in June based on a data cut-off dated May 6<sup>th</sup> 2019 with 121 patients treated, out of which 108 patients had received two or more cycles of treatment.

Oncopeptides has initiated preparations for submitting a New Drug Application (NDA) for accelerated approval of melflufen in the US based on the available HORIZON data. The detailed plan for the filing process is still under development, but Oncopeptides currently targets to submit the application to FDA during the first quarter of 2020. This could then lead to the first melflufen market approval in the US in 2020.

More information can be found at: <https://clinicaltrials.gov/ct2/show/NCT02963493?term=melflufen&rank=2>

### **About Melflufen**

Melflufen is a lipophilic peptide-conjugated alkylator that rapidly delivers a highly cytotoxic payload into myeloma cells through peptidase activity. It belongs to the novel class Peptidase Enhanced Cytotoxics (PEnC), which is a family of lipophilic peptides that exhibit increased activity via peptidase cleavage and have the potential to treat many cancers. Peptidases play a key role in protein homeostasis and feature in cellular processes such as cell-cycle progression and programmed cell death. Melflufen is rapidly taken up by myeloma cells due to its high lipophilicity and immediately cleaved by peptidases to deliver an entrapped hydrophilic alkylator payload. In vitro, melflufen is 50-fold more potent in myeloma cells than the alkylator payload itself due to the peptidase cleavage, and induces irreversible DNA damage and apoptosis. 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.

### **About Oncopeptides**

Oncopeptides is a pharmaceutical company focused on the development of targeted therapies for difficult-to-treat hematological cancers. The company is focusing on the development of the lead product candidate melflufen, a novel lipophilic peptide conjugated alkylator, belonging to a new class of drugs called Peptidase Enhanced Cytotoxics (PEnC). Melflufen is in development as a new treatment for the hematological cancer multiple myeloma, including the Phase 2 pivotal trial HORIZON currently underway and a global confirmatory Phase 3 trial (OP-103 OCEAN) continuing enrollment. Oncopeptides' headquarters is located in Stockholm, Sweden, and the company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO.

### **For further information, please contact:**

Jakob Lindberg, CEO of Oncopeptides

E-mail: [jakob.lindberg@oncopeptides.com](mailto:jakob.lindberg@oncopeptides.com)

Telephone: +46 8 615 20 40

Rein Piir, Head of Investor Relations at Oncopeptides

E-mail: [rein.piir@oncopeptides.com](mailto:rein.piir@oncopeptides.com)

Cell phone: +46 70 853 72 92

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