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New Data from Oncopeptides Phase 1/2 O-12-M1 Trial Evaluating Melflufen in RRMM Presented at 2019 ASCO Annual Meeting

Stockholm - 3 June 2019 - Oncopeptides AB (Nasdaq Stockholm: ONCO), a pharmaceutical company focused on the development of targeted therapies for difficult-to-treat hematological cancers, announced today new data presented at the the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting from its Phase 1/2 O-12-M1 clinical study of lead candidate melflufen. The data demonstrate that melflufen may offer positive disease stabilization and favorable time to next treatment (TTNT) outcomes in heavily-pretreated patients with relapsed/refractory multiple myeloma (RRMM).

Overall conclusions from the data presented include:

- Melflufen plus dexamethasone treatment results in disease stabilization in 76% of RRMM patients, which translates to a median TTNT of 7.9 months (10.6 months when censoring at time of death), which compares favorably with other relevant trials.
- A median OS of 20.7 months in an advanced RRMM population, suggesting that melflufen therapy is associated with a long-term benefit and allows patients to receive further treatment to control disease.
- Results support those of previous data showing the promising efficacy profile of melflufen for the treatment of RRMM.

The data is presented by Professor Paul G. Richardson, MD, RJ Corman Professor of Medicine at Harvard Medical School and Director of Clinical Research at the Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute, Boston, USA.

Oncopeptides recently announced that, following discussions with the U.S. Food & Drug Administration (FDA), the company has initiated the preparation for submitting a New Drug Application (NDA) for accelerated approval of melflufen for the treatment of patients with triple-class refractory multiple myeloma. The company targets to submit the application in the first quarter of 2020 based on the positive data from the ongoing Phase 2 HORIZON clinical trial.

“We are committed in helping patients with myeloma get access to melflufen given the safety and efficacy profile that is emerging from our clinical trials,” said Jakob Lindberg, CEO of Oncopeptides. ”In addition to the data presented at ASCO, data from the melflufen clinical programs have also been selected for four presentations at the 2019 EHA Annual Congress, including updated data from the HORIZON Phase 2 pivotal clinical trial that will serve as the foundation for our NDA submission.”

The full poster presented at the 2019 ASCO Annual Meeting can be found on the company webpage under:
www.oncopeptides.com / Investors & Media / Presentations / 2019 ASCO Annual Meeting - poster

About the O-12-M1 Clinical Trial

O-12-M1 is a Phase 1/2 study with melflufen plus dexamethasone in 62 patients with RRMM who had ≥2 prior lines of therapy, prior exposure to at least an IMiD and a proteasome inhibitor, and disease progression on last line of therapy. Final study results were presented at the 2017 American Society of Hematology (ASH) Annual Meeting.

Summary of O-12-M1 Data

At the time of data cutoff on November 9, 2017, 45 patients had been treated with 40 mg melflufen and dexamethosone. Median age was 66 years (47-78). 60% of patients were ISS stage II/III and 44% were high-risk cytogenetics. Patients had four median prior lines of therapy, with 91% of patients being single refractory, 67% of patients double refractory and 7% triple refractory. Further, 53% of patients were alkylator refractory. At data cutoff, 44 pts (98%) discontinued melflufen + dexamethasone, mainly due to adverse events (40%) and PD (31%). 27 patients received subsequent therapy. Median time from start of melflufen and dexamethasone to first subsequent therapy or death (TTNT), whichever occurred first, was 7.9 months (95% CI: 5.68-11.01). The majority of patients' (52%) next therapy was single-agent with or without steroid therapy, and approximately half of patients receiving subsequent therapy (44%) received at least two subsequent lines of therapy.

Table: TTNT with Melflufen in O-12-M1 and Other Agents in RRMM

Agent or Regimen	No. of Patients	Prior Lines of Therapy	Death as an Event or Censored	Median TTNT, mo
Melflufen	45	4	Censored	10.6
Pomalidomide or carfilzomib[17]	Pomalidomide: 264 Carfilzomib: 190	2+	Censored	Pomalidomide: 11.9 Carfilzomib: 9.4
Melflufen	45	4	Event	7.9
VRd or KRd[18]	VRd: 343 KRd: 139	1-3	Event	VRd: 12.9 KRd: 8.7
Daratumumab[19]	126	4	Event	5.9

KRd, carfilzomib + lenalidomide + dexamethasone; RRMM, relapsed/refractory multiple myeloma; TTNT, time to next treatment; VRd, bortezomib + lenalidomide + dexamethasone.

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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 (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.

Visit www.oncopeptides.com for more information.