

Patient recruitment in the Pivotal Phase 2-Study HORIZON completed

Stockholm - September 26, 2019 - Oncopeptides AB (Nasdaq Stockholm: ONCO) announced today that the last patient has been included in the OP-106 HORIZON pivotal phase 2 clinical study evaluating melflufen with dexamethasone in patients with relapsed/refractory multiple myeloma (RRMM). Oncopeptides has previously communicated a target enrollment of 150 patients in the study before the end of September, which now has been achieved.

Oncopeptides is engaged in preparations for submitting a New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) for accelerated market approval in the United States based on available data from the HORIZON study. The objective is to submit the application in the first quarter of 2020. This could then potentially lead to the first market approval for melflufen in the U.S. in 2020.

“The HORIZON study was initially intended as an exploratory study in late-stage patients with relapsed and/or refractory multiple myeloma when started in January 2017. As positive efficacy and safety data were generated, the study was expanded to include 150 patients and now forms the basis of our planned application for accelerated market approval in the United States. We are encouraged that the data to-date support the potential for melflufen to offer a new treatment option in this important setting, especially for patients with severe and widespread multiple myeloma. This is an important milestone in Oncopeptides’ history and signifies that we are on track for submitting our NDA in the U.S. as planned, which will completely transform the company if approved,” says Jakob Lindberg, CEO of Oncopeptides.

About the OP-106 HORIZON study

Patient recruitment in the pivotal HORIZON study is now completed. The patients in the study are refractory to pomalidomide and/or daratumumab after failing on immunomodulatory drugs (IMiDs) and proteasome inhibitors (PIs). The interim data presented at IMW 2019 was based on a data cut-off dated July 30, 2019, with 136 patients treated. The goal is to present updated data at the American Society of Hematology (ASH) annual meeting in December, pending abstract acceptance.

More information on the IMW 2019 presentation can be found at:

<https://www.oncopeptides.se/en/new-interim-data-in-rrmm-patients-with-extramedullary-disease-from-the-pivotal-phase-2-horizon-study-presented-at-international-myeloma-workshop/>

More information can be found at:

<https://clinicaltrials.gov/ct2/show/NCT02963493?term=melflufen&rank=2>

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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.

For more information please visit www.oncopeptides.com.