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Oncopeptides reinitiates patient enrollment to the melflufen clinical program following a temporary pause due to the COVID-19 pandemic

STOCKHOLM — May 28, 2020 — Oncopeptides AB (Nasdaq Stockholm: ONCO) announces that the company starts patient enrollment to its clinical program following the temporary recruitment pause due to the COVID-19 pandemic, announced on March 20. The program will be reinitiated at sites where local regulations and patient safety enable a restart and where recruitment, treatment and adherence to protocol, as well as safety and data monitoring are feasible.

The temporary pause did not impact the pivotal phase 2 HORIZON study and the company is on track to submit a file to the FDA based on these data by the end of Q2.

“Relapsed and refractory multiple myeloma is a life-threatening disease with limited treatment alternatives in later stages. A clinical trial may offer patients new treatment options. The pandemic has had a major impact on clinical trial activities with many of them closed to recruitment or halted. As the general situation now is improving, clinical trials can be re-initiated in regions where the potential risk-benefit for the patient is positive”, says Luděk Pour, MD, PhD, Clinic of Internal Medicine - Hematology and Oncology, University Hospital Brno, Czech Republic.

Patient enrollment will start as soon as possible in the following studies; the ANCHOR combination study, the BRIDGE study and the AL Amyloidosis study. The LIGHTHOUSE combination study will start after the summer. Oncopeptides will provide updated guidance on timelines, once the studies have been reinitiated.

“I am really pleased that despite the ongoing pandemic we can restart our clinical program for melflufen in a safe and responsible way,” says Klaas Bakker, MD, PhD, Chief Medical Officer of Oncopeptides. “There is a significant unmet medical need of new therapies for patients with relapsed refractory multiple myeloma who in several cases not have any treatment options left. Also, I am very pleased to be able to continue the AL amyloidosis study, where the unmet medical need is particularly high”.

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The information in the press release is information that Oncopeptides is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person above, on May 28, 2020 at 08.00 (CET).

About melflufen

Melflufen (melphalan flufenamide) is a first-in-class anti-cancer peptide-drug conjugate that rapidly delivers an alkylating payload into tumor cells. Melflufen is rapidly taken up by myeloma cells due to its high lipophilicity and is immediately cleaved by peptidases to deliver an entrapped hydrophilic alkylator payload. Peptidases play a key role in protein homeostasis and feature in cellular processes such as cell-cycle progression and programmed cell death. 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.

About Oncopeptides

Oncopeptides is a pharmaceutical company focused on the development of targeted therapies for difficult-to-treat hematological diseases. The company is focusing on the development of the lead product candidate melflufen, a first-in-class anti-cancer peptide-drug conjugate that rapidly delivers an alkylating payload into tumor cells. Melflufen (melphalan flufenamide) is in development as a new treatment for the hematological cancer multiple myeloma and is currently being evaluated in multiple clinical studies including the pivotal phase 2 HORIZON study and the ongoing phase 3 OCEAN study. Oncopeptides' headquarters is in Stockholm, Sweden with U.S. headquarters 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.