

Oncopeptides provides update regarding COVID-19 impact on the melflufen clinical program

STOCKHOLM — March 20, 2020 — Oncopeptides AB (Nasdaq Stockholm: ONCO) announced today measures the company is taking in response to the global spread of the novel coronavirus (COVID-19) pandemic. Most importantly, the pivotal phase 2 HORIZON study will not be affected and FDA submission plans are on track for a filing late Q2. The phase 3 OCEAN study with 423 out of 450 planned patients enrolled will remain open for patient enrolment. Topline results are expected to be only slightly delayed. Recruitment for other ongoing clinical studies will be put on temporary pause for patient safety reasons, including the phase 2 ANCHOR and BRIDGE studies and the recently started AL Amyloidosis study. The initiation of new studies including LIGHTHOUSE is expected to be delayed. Treatment will continue for all patients currently enrolled in clinical studies.

The COVID-19 pandemic is evolving rapidly and will have a significant impact on the global healthcare system. Many hospitals, regions and countries are updating their guidelines and Oncopeptides is taking necessary steps to fully comply with new guidance. Oncopeptides' primary obligation is to avoid unnecessary exposure in an at-risk population while maintaining study data integrity. The company has therefore taken the following actions that impact the company's clinical programs:

- The pivotal phase 2 HORIZON study is not affected. The study was fully recruited in September 2019 and the data cut for final read-out was made on January 14. The data analysis is now in final stages and release of topline data is expected shortly. The timeline for the accelerated approval process remains intact with submission expected in Q2 2020.
- The phase 3 OCEAN study will continue to enroll patients in line with regulatory guidelines and site capabilities. The study is in the final stages of recruitment with 423 patients of a planned total of 450 enrolled. At the current patient recruitment pace the last patient is expected to be enrolled in April but patient recruitment could slow down further. The number of patients currently enrolled is sufficient to reach the study endpoint that requires 339 progression events.
- The ANCHOR combination study cohort with melflufen+daratumumab is fully enrolled; however, recruitment of the melflufen+bortezomib cohort has been paused temporarily.
- The BRIDGE study has put recruitment on temporary pause.
- The AL Amyloidosis study has put recruitment on temporary pause.
- No new studies will be initiated during this period, including LIGHTHOUSE that otherwise is ready for initiation.

Treatment will continue for all patients currently enrolled in clinical studies.

Jakob Lindberg, CEO comments:

“Obviously the COVID-19 pandemic has an enormous impact on us and society as a whole. We are very fortunate that this does not slow down our application process for accelerated approval in US and will not delay us in our effort to bring melflufen to the myeloma patients. We are equally fortunate that recruitment in OCEAN has remained relatively strong the last few weeks and we have enrolled sufficient number of patients to assess our primary endpoint in the future. The COVID-19 public health crisis does not decrease the medical need of myeloma patients and I firmly believe that melflufen has the potential to offer a new option to those with few available treatments. The safety and well-being of our patients continues to be our top priority and we will continue to take appropriate actions if need be to ensure their safety.”

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This information 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 persons set out above, at 08:00 CET on March 20, 2020.

About melflufen

Melflufen (INN 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 is in development as a new treatment for the hematological cancer multiple myeloma and is currently being tested 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.