

## **Oncopeptides to Apply for Accelerated Approval in the US**

**Stockholm – May 20, 2019 - Oncopeptides AB (Nasdaq Stockholm: ONCO) announced today that, after discussions with the 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.**

During the spring, Oncopeptides has been engaged in dialogue with the FDA to explore whether melflufen could be eligible for accelerated approval based on the promising data generated in the ongoing phase 2 HORIZON clinical trial. The target indication would be for the treatment of patients with relapsed refractory multiple myeloma whose disease is triple-class refractory (i.e. refractory to at least one IMiD, one proteasome inhibitor and one anti-CD38 monoclonal antibody). In the discussions, the FDA has requested and received all available clinical data at hand for melflufen.

As a result of the dialogue with the FDA, Oncopeptides has initiated preparations for an NDA submission 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 during the first quarter of 2020. This could then lead to the first melflufen market approval in the US in 2020.

“We are very excited over the opportunity to help patients with triple-class refractory multiple myeloma who currently have very limited treatment options to potentially access a new treatment alternative that may have a large impact on their lives. The outcome of the regulatory discussions during the spring is even better than we anticipated and is a major milestone for Oncopeptides as it means that we can start the application process and potentially attain market approval significantly earlier than planned,” says Jakob Lindberg, CEO of Oncopeptides.

“Potential approval will of course depend on the formal FDA review once we have submitted the application, but based on the discussions and the data at hand, we believe we have a very good chance to secure an approval, provided that the results generated in the HORIZON trial continue to be in line with the data we have seen so far. It will therefore be very exciting to present updated HORIZON data at the European Hematology Association (EHA) meeting in Amsterdam on June 16,” concludes Jakob Lindberg.

### **Conference call for investors, analysts and the media**

Oncopeptides will host a conference call and present an operational update on Tuesday May 21, 2019 at 10:00 (CET). It will be presented by CEO Jakob Lindberg and members of the Oncopeptides management team. The conference call will also be streamed via a link on the website: [www.oncopeptides.com](http://www.oncopeptides.com).

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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 20, 2019 at 18.00 (CET).

**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 of 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 is 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 developing drugs for the treatment of cancer. 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 and is currently being tested in a global pivotal phase 3 trial called OCEAN, a phase 2 trial called HORIZON and in two additional supporting clinical trials. 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](http://www.oncopeptides.com) for more information.**