



Stockholm, Sweden

Press release 24 April 2019

## **Oncopeptides provides new guidance on the patient recruitment in the OCEAN study and a clinical program update in a webcast at 10:00 (CET)**

**Stockholm – 24 April 2019 - Oncopeptides AB (Nasdaq Stockholm: ONCO) announces today that the company will provide an update on patient recruitment in the ongoing phase 3 study OCEAN, as well as a general update from all the company's clinical studies in a webcast at 10.00am (CET) today.**

**Conference call for investors, analysts and the media, Wednesday, 24 April 2019, at 10 am (CET).** CEO Jakob Lindberg will provide an overview of ongoing clinical studies and activities in connection with these.

Phone numbers for participants from:

Sweden: +46850558357

Europe: +443333009030

USA: +18335268382

The conference call will also be streamed on the website [www.oncopeptides.com](http://www.oncopeptides.com) and via the link below.

<https://tv.streamfabriken.com/2019-04-24-oncopeptides-press-conference>

### **OCEAN**

In the second half of 2018, Oncopeptides communicated that the patient recruitment rate in the company's phase 3 study OCEAN was lower than initially estimated when the study was initiated in 2017. The company implemented a number of measures to increase patient recruitment in 2018. For example, the number of hospitals participating in the study was increased by almost 50% and hospitals are still being added. These activities have been effective, and the recruitment rate has increased significantly. However, they have not entirely made up for the deviation from the initial forecast and the company now estimates that the last patient in (LPI) will take place during Q1 2020, which corresponds to a delay of 6 to 9 months compared to previously communicated timelines.

“After the initiation of OCEAN, pomalidomide has been used more and more as a second line treatment option for patients with multiple myeloma. This is a strong positive for melflufen and its future sales potential based on the OCEAN trial design as a head-to-head comparison with pomalidomide. At the same time as being positive for the value of OCEAN it also represents a patient recruitment challenge since those patients cannot be part of the OCEAN study. It takes time to establish a new recruitment forecast since patient recruitment variability is high between different months and is further amplified by the expansion of the number of hospitals in the study. Despite all the actions taken, we have now determined that we will not meet the original enrollment goal”, commented Jakob Lindberg, CEO of Oncopeptides.

### **HORIZON**

In late summer 2018, Oncopeptides decided to expand the study from 80 to 150 RRMM patients in order to provide a more extensive and robust dataset. This decision was based on the promising clinical data presented during 2018. The study has attracted significant interest among treating physicians and new clinical centers have been added. The company estimates that the last patient entering the study will take place during Q3, which is in line with previous forecasts.

By increasing the number of patients in the study to collect a larger amount of clinical data, the study becomes more relevant from a regulatory point of view. As previously communicated in the year-end report, the plan is to

discuss these promising data with regulatory authorities including the FDA. A meeting with the FDA has now been scheduled and will be held before the summer.

### **ANCHOR**

The combination study where melflufen is used together with dexamethasone and either daratumumab or bortezomib in RRMM patients has started well, and initial results from the phase 1 part were presented at ASH in December 2018. There is a large interest for this study, in particular in combination with daratumumab, and the phase 2 part is now ongoing. Tolerability and clinical activity look promising in both groups. Based on the promising preliminary results and the large interest in treating RRMM patients with melflufen together with daratumumab, Oncopeptides is planning to start a phase 3 study with this combination later this year.

### **BRIDGE**

The study in RRMM patients with impaired renal function started as planned in the autumn of 2018. An update of the protocol has been conducted, prompted by the FDA, which will soon allow patients with both moderate and severe renal impairment to be treated with melflufen. The study is planned to be fully recruited in the autumn of 2019, in line with our original forecast.

#### **For more information, please contact:**

Jakob Lindberg, CEO of Oncopeptides

Telephone: +46 8 615 20 40

E-mail: [jakob.lindberg@oncopeptides.com](mailto:jakob.lindberg@oncopeptides.com)

Rein Piir, Head of Investor Relations at Oncopeptides

Cell phone: +46 70 853 72 92

E-mail: [rein.piir@oncopeptides.com](mailto:rein.piir@oncopeptides.com)

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 April 24, 2019 at 07.30 (CET).

### **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 peptide conjugated alkylator, belonging to a new class of drugs called Peptidase Enhanced Compounds (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 and in three 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.

**More information is available on [www.oncopeptides.com](http://www.oncopeptides.com).**