

Stockholm, Sweden

Press release September 18, 2018

# First patient starts treatment with Ygalo® in Oncopeptides' Phase II study BRIDGE in RRMM patients with renal impairment

Stockholm – 18 September 2018 – Oncopeptides AB (Nasdaq Stockholm: ONCO) today announced that the first patient has started treatment in the company's Phase II BRIDGE trial designed to study the Pharmacokinetics (PK), safety and efficacy of Ygalo® in combination with dexamethasone in multiple myeloma patients with renal impairment.

Multiple myeloma commonly results in deteriorating renal function. This makes BRIDGE an important study to show treating physicians how Ygalo® can be used in Relapsed Refractory Multiple Myeloma (RRMM) patients with renal impairment.

#### **CEO** comment

"In addition to our pivotal study OCEAN, this is the third ongoing clinical trial to gather information about Ygalo® in different groups of myeloma patients. It is important to map out Ygalo's efficacy and side effect profile in myeloma patients at various stages of the disease to guide treating physicians about Ygalo's clinical benefit profile. The BRIDGE study is an important positioning study since it seems Ygalo's treatment profile does not vary with kidney function in the same way as for other multiple myeloma treatments that has limitations in use or effect in these patients" said Jakob Lindberg, CEO of Oncopeptides.

## Ygalo® in clinical development

Ygalo® has been investigated in the treatment of late-stage relapsed refractory multiple myeloma (RRMM) patients. This was done in the clinical study O-12-M1 where strong final results were reported in December 2017. Currently, four clinical studies, including BRIDGE, are ongoing with Ygalo®.

In the **BRIDGE** study the pharmacokinetics (PK), safety and also efficacy will be evaluated in RRMM patients, also suffering from renal impairment, a common complication in MM patients, Ygalo® is administered together with dexamethasone.

**ANCHOR** is a Phase I/II study, where Ygalo® is administered in combination with either bortezomib+dexamethasone or daratumumab+dexamethasone in RMM or RRMM patients. The results from this study aim to create understanding and knowledge among treating physicians for how Ygalo® can be used in combination with these drugs. In addition, the results could open up for the use of Ygalo® in earlier lines of treatment.

**HORIZON** is a Phase II study that studies the effect of Ygalo® in late-stage RRMM patients with few or no remaining established treatment options. Interim data from this study was reported in June 2018 at the European Hematology Association meeting (EHA).

**OCEAN** is Oncopeptides' pivotal Phase III study where Ygalo® is compared directly head-to-head with current standard of care, pomalidomide, in late-stage RRMM patients.

#### **FACTS - BRIDGE**

- Performed in Europe
- Phase II study that will include 25 patients
- o A PK study in which Ygalo® is administered together with dexamethasone (steroid)
- o The study will show how Ygalo® should be used in patients with renal impairment
- o Results are expected late 2019
- BRIDGE will increase Ygalos market opportunity by opening up for use in patients with renal impairment,
  which is a common complication in patients with multiple myeloma

#### For further information, please contact or visit www.oncopeptides.se:

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The information was submitted through the agency of the contact person above for publication at 11.30 CET on September 18, 2018.

## About Ygalo®

Ygalo®, an alkylating peptide, belongs to a novel class of peptidase-enhanced compounds (PEnCs) and targets the multiple myeloma (MM) tumor transformation process with a unique mechanism of action. Aminopeptidases are heavily over-expressed in MM and are key to the transformational process of the tumor cells. Ygalo® selectively targets MM through aminopeptidase-driven accumulation; in vitro experiments show a 50-fold enrichment of alkylating metabolites in MM cells. The enrichment results in selective cytotoxicity (increased ontarget potency and decreased off-target toxicity), and that resistance pathways of existing myeloma treatments (including alkylators) is overcome. Ygalo® also demonstrates strong anti-angiogenic properties.

# About Multiple Myeloma

Multiple myeloma is a hematological cancer of the B-cells (antibody producing cells) with no cure. Currently, the median overall survival is roughly 5 years and improving (Source: National Cancer Institute).

Today, approximately 170,000 patients live with multiple myeloma in the EU and the US while 57,000 patients get diagnosed and 26,000 patients die from the disease annually (Source: American Cancer Society, Global Data 2015 and National Cancer Institute). The underlying increase in number of multiple myeloma patients is slightly more than 1% per year where an aging population is the main reason for growth. However, the growth in late-stage multiple myeloma patients, which is studied in the OCEAN trial with Ygalo®, is more than 10% per year due to improvements in earlier lines of therapy, i.e. more patients survive the first years with multiple myeloma and become late-stage multi-refractory patients with a significant medical need for more treatment options.

#### **Treating Multiple Myeloma**

Multiple myeloma is mainly treated through five different treatment modalities – alkylators, CD-38 binding antibodies, IMiDs, proteasome inhibitors and steroids. Due to the high mutation frequency of myeloma cells, patients have several different active cancers (cancer cell clones) at the same time with different protein expression patterns. Because of this heterogeneity of the disease in each patient, broad spectrum agents such as alkylators, IMiDs, proteasome inhibitors and steroids are the back-bone in multiple myeloma treatment. In the case of the new targeted agents, they will predominantly be used in combination with broad spectrum agents to ensure that all the patient's cancer cells get appropriately treated. Immuno-oncological compounds have so far had limited success in the treatment of multiple myeloma.

# **About Oncopeptides**

Oncopeptides is a research and development stage pharmaceutical company developing drugs for the treatment of cancer. The company focus on the development of the lead product candidate Ygalo®, an alkylating peptide, Peptidase Enhanced Compounds (PEnCs). Ygalo® is intended as an effective treatment of hematological cancers, and in particular multiple myeloma. The current clinical study program is intended to demonstrate better results from treatment with Ygalo® compared with established alternative drugs for patients with late-stage multiple myeloma. Ygalo® will potentially provide physicians with a new treatment option for patients suffering from this serious disease.

For more information: www.oncopeptides.se