

Stockholm, Sweden

Press release April 12, 2018

# First patient starts treatment in Oncopeptides' Phase I / II ANCHOR study with Ygalo®

Stockholm - 12 April 2018 - Oncopeptides AB (Nasdaq Stockholm: ONCO) today announced that the first patient has started treatment in the company's Phase I / II ANCHOR trial designed to study Ygalo<sup>®</sup> in multiple myeloma patients in combination with other drugs. This is an important study for creating understanding and knowledge among treating physicians for how Ygalo<sup>®</sup> can be used in Relapsed (RMM) and Relapsed Refractory Multiple Myeloma (RRMM) patients, and to open up for Ygalo<sup>®</sup> as a treatment option in earlier lines of treatment.

# Ygalo® in clinical development

Ygalo<sup>®</sup> 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, three clinical studies, including ANCHOR, are ongoing with Ygalo<sup>®</sup>.

In the *ANCHOR* study, Ygalo<sup>®</sup> will be administered in combination with either bortezomib or daratumumab in RMM or RRMM patients. The results of this study aim to create understanding and knowledge among treating physicians for how Ygalo<sup>®</sup> can be used in combination with these drugs. In addition, the results could open up for the use of Ygalo<sup>®</sup> in earlier lines of treatment.

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

*HORIZON* is a Phase II study that studies the effect of Ygalo<sup>®</sup> in late-stage RRMM patients with few or no remaining established treatment options. Interim data from this study was reported in December 2017.

# **CEO** comment

"Now, all clinical studies have been initiated in accordance with the plans that we communicated in conjunction with our IPO last year. In addition, the recently executed targeted share issue enables us to build-up our medical relations and commercial organization to prepare for a potential future successful launch with initial focus on the US. The recruitment of Dr. Christian Jacques as EVP Clinical Strategy and Chief Scientific Officer is an important strategic part of this organizational build-up. Dr Jacques will, among other things, continue to develop our clinical development strategy for Ygalo<sup>®</sup> and other pipeline candidates." said Jakob Lindberg, CEO of Oncopeptides.

# **FACTS - ANCHOR**

o Performed in Europe and the United States

o Phase I / II study that will include up to 64 patients

o ANCHOR is an open, single-arm study, in which Ygalo<sup>®</sup> and dexamethasone (steroid) is administered in combination with bortezomib or daratumumab

o The study will show how Ygalo<sup>®</sup> should be used as combination therapy with daratumumab and bortezomib o Results are expected 2019/2020 from Phase I and Phase II respectively

o ANCHOR will increase Ygalos market opportunity by opening up for use in earlier lines of therapy, as combination therapies



## 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 16.00 CET on April 12, 2018.

## About Ygalo®

Ygalo<sup>®</sup> is a next generation alkylator treatment, a peptidase enhanced cytotoxic (PEnC), that targets cancer cells through a mechanism called peptidase potentiation. In cell culture studies, traditional alkylators target the bone marrow (which causes side effects) and cancer cells (which treats the disease) equally well. In contrast, Ygalo<sup>®</sup> targets the cancer cells 50x better than the bone-marrow cells.

## 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<sup>®</sup>, 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. Since the founding of the company, the focus has primarily been on the development of the lead product candidate Ygalo<sup>®</sup>, an innovative, peptidase-potentiated alkylator intended for effective and focused treatment of hematological cancers, and in particular multiple myeloma. The current clinical study program of Ygalo<sup>®</sup> is intended to demonstrate better results from treatment with Ygalo<sup>®</sup> compared to established alternative drugs for patients with late-stage multiple myeloma. Ygalo<sup>®</sup> could potentially provide physicians with a new treatment option for patients suffering from this serious disease.