

Oncopeptides presented survival data from the phase II-study O-12-M1 of Ygalo® (melflufen) at the 59th Annual Meeting of ASH today

Stockholm – December 10th, 2017 - Oncopeptides AB (Nasdaq Stockholm: ONCO) announced today that the first survival data were presented at the annual meeting of the American Society of Hematology from the phase II-study O-12-M1 in late-stage patients with Relapsed Refractory Multiple Myeloma (RRMM).

Summary of key results presented

The results show a median progression-free survival (PFS) of 5.7 months, a median overall survival (OS) of 20.7 months and an overall response rate of 31%. The data are very encouraging and compares favorably with other clinical studies in this patient population.

CEO comments on O-12-M1

"Myeloma patients that primarily are treated with lenalidomide and proteasome inhibitors through several lines of therapy and suffer from disease progression in conjunction with treatment have deteriorating prognosis and a significant medical need. In the clinical study O-12-M1, we have studied the efficacy of Ygalo® in these advanced stage patients. The results show a median OS of 20.7 months, median PFS of 5.7 months and ORR of 31%. Tolerability profile was good with patients receiving monthly doses of Ygalo® for a median of 5 cycles. These data compare favorably with other clinical studies in this patient group, especially when considering that 44% of patients in O-12-M1 also had failed on pomalidomide. The data provides us with an increasing degree of comfort regarding the outcome of our Phase III program OCEAN and a role for Ygalo® in the treatment of late-stage myeloma patients" said Jakob Lindberg, CEO of Oncopeptides.

The poster presented at ASH can be found at: www.oncopeptides.se/presentations/ASH

Conference call for investors, analysts and the media

Jakob Lindberg, CEO at Oncopeptides will summarize impressions from the ASH Annual Meeting and will review and comment on relevant data from the conference including a summary of the survival data from the O-12-M1 study and interim data from the ongoing HORIZON study.

Time: Wednesday, 13th December 2017, at 14.30 (CET).

Phone numbers for participants from:

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The conference call will also be streamed via a link on the website: www.oncopeptides.se and the presentation will be available on Oncopeptides website after completion of the telephone conference.

About the O-12-M1 study

Enrolment

Patient enrolment in the study was completed in December 2016. In total, 45 patients were included with data cut-off of 9th November 2017. One patient was still in treatment at time of data cut-off.

Methods

Ygalo® (Melflufen) 40 mg was administered intravenously on Day 1 of each 28-day cycle together with dexamethasone 40 mg weekly for up to 8 cycles or longer. Patients had relapsed-refractory MM (RRMM) with measurable disease, ≥2 prior lines of therapy including lenalidomide and bortezomib, and disease progression on or within 60 days of completion of last therapy. After disease progression (PD) or start of subsequent therapy, patients were followed for survival every 3 months for up to 24 months. The median number of prior lines of therapy was four.

Of the treated patients, 64% were double refractory immunomodulatory drugs (IMiDs) and a proteasome inhibitors (PIs), 93% were last line refractory and 44% were pomalidomide refractory. Patients were treated with a median of 5 cycles of Ygalo® and the median treatment duration was 16 weeks.

Results - Efficacy conclusions regarding O-12-M1

Treatment with Ygalo®, a peptidase enhanced Cytotoxics (PEnCs), shows long-term benefit in late-stage RRMM patients where conventional therapies have failed. Both the median PFS and OS in this heavily pre-treated population, with limited remaining treatment options, are encouraging, standing at 5.7 months and 20.7 months respectively. The long median OS of 30.2 months in patients that achieved stable disease (SD) as best response will be studied further in the ongoing studies OCEAN (phase III) and HORIZON (phase II).

Overall response rate (efficacy evaluable and all treated patients)

| N | PD | SD | MR | PR | VGPR | ORR | CBR |
|----------------------------------|----|----|----|----|------|-----|-----|
| ITT (N = 45)* | 7 | 12 | 8 | 9 | 5 | 31% | 49% |
| Efficacy evaluable** (N = 34) | 1 | 11 | 8 | 9 | 5 | 41% | 65% |

*Four patients did not have a response assessment

** patients receiving two doses of Ygalo®

Safety

The treatment was well tolerated in this late stage patient population. Reversible and clinically manageable hematologic toxicity was the most common AE type. Non-hematologic AEs were infrequent.

About Ygalo®

Ygalo® is a next generation alkylator compound that targets cancer cells through a mechanism called Peptidase Enhanced Cytotoxics (PEnCs). In cell culture studies, traditional alkylators target cancer cells (which treats the disease) and also bone marrow cells (which causes side effects) to an equal degree. In contrast, Ygalo® targets the myeloma cells 50x better than the bone-marrow cells.

Ygalo® in clinical development

Ygalo® has been used to treat late-stage RRMM patients in both phase I and phase II clinical studies with favorable results. Currently, Ygalo® is being studied in three clinical trials for the treatment of multiple myeloma.



The current studies are O-12-M1, HORIZON and OCEAN. A fourth study, ANCHOR, will be initiated early 2018 to further investigate Ygalo® as part of combination therapies in multiple myeloma.

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 - US).

Today, approximately 170,000 patients live with multiple myeloma in the EU and the US while 57,000 patients are newly 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 the 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, that is the focus area for 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 further 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 its 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 are appropriately treated. Immuno-oncological compounds have so far had limited success in the treatment of the disease.

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®, an innovative, Peptidase Enhanced Cytotoxics (PEncs) intended for effective and focused 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 to established alternative drugs for patients with late-stage multiple myeloma. Ygalo® could potentially provide physicians with a new treatment option for patients suffering from this serious disease.

Visit www.oncopeptides.se for more information.

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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 December 10, 2017 at 15.00 p.m. (CET).