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Oncopeptides presents first interim data from the ongoing combination trial ANCHOR with melflufen at the 60th American Society of Hematology Meeting

Stockholm – December 1, 2018 – Oncopeptides AB (Nasdaq Stockholm: ONCO) announced today a presentation of the first interim data with melflufen (Ygalo®) from the ongoing phase I/II study ANCHOR at the 60th ASH meeting in San Diego, California, USA.

Overall conclusions

- *The combinations of melflufen and dexamethasone (dex) with either bortezomib or daratumumab in relapsed-refractory multiple myeloma (RRMM) patients are well tolerated*
- *No dose limiting toxicity has been observed at the melflufen 30 and 40 mg dose levels in either regimens. The 40 mg dose level is still recruiting patients*
- *An Overall Response Rate (ORR) of 86% was observed with melflufen and dexamethasone in combination with daratumumab (CD38-directed monoclonal antibody)*
- *An Overall Response Rate (ORR) of 100% was observed with melflufen and dexamethasone in combination with bortezomib (proteasome inhibitor)*

The data are presented in a poster that can be found at: www.oncopeptides.com / presentations / 60th ASH

CEO comments

"Although, these are early data and small patient samples, it is encouraging to see that melflufen is well tolerated and has a very high level of activity with no cross resistant pattern in combination regimens. These patients have undergone 2-3 prior lines of therapy and have developed resistant disease. The interim data show a very good efficacy profile for melflufen in combination with either bortezomib or daratumumab. In a cross-study comparison in RRMM patients treated with combination regimens our interim data with an ORR in the range 86-100% stand out positively. The treatment landscape changes over time and there is a high need of new treatment options with a novel mechanism of action like melflufen" said Jakob Lindberg, CEO of Oncopeptides.

About the ANCHOR study

The study recruitment is ongoing. ANCHOR is a phase I/II study where melflufen and dexamethasone (dex) is dosed in combination with either bortezomib or daratumumab. All patients must have 1-4 prior lines of therapy and be refractory (or intolerant) to an immunomodulary agent (IMiD) or a proteasome inhibitor (PI) or both.

In combination with bortezomib (Regimen A) patients cannot be refractory to a PI and in combination with daratumumab (Regimen B) patients cannot be previously exposed to any anti-CD38. Patients will be treated until documented disease progression or unacceptable toxicity. The primary objective of the phase I part of the study is to determine the optimal dose of melflufen and dex, up to a maximum of 40 mg, in combination with bortezomib or daratumumab. An additional 20 patients per regimen will be recruited in the phase II part of the study where the primary objective is ORR.

Summary of the ANCHOR interim data

Melflufen in combination with bortezomib - Regimen A

At the time of the data cut-off November 12, 2018, 3 patients had been treated with 30 mg melflufen and dex in combination with bortezomib. Median age was 81 years with a median of 3 prior lines of therapy. All patients were relapsed-refractory and 2 out of 3 patients were last line refractory (disease progression while on therapy). All patients were ongoing at the time of the data cut-off with a median treatment duration of 5.8 months.

The patients received a total of 17 cycles of treatment with a median of 7. All 3 patients achieved partial response (PR). No dose limiting toxicities were observed at the 30 mg melflufen dose level and the melflufen 40 mg has been opened for enrollment. The regimen was well tolerated with clinically manageable G3/4 hematological AEs and the low number of non-hematological AEs was noteworthy.

Melflufen in combination with daratumumab - Regimen B

At the time of the data cut-off, November 12, 2018, 9 patients had been treated with melflufen in combination with daratumumab and dex. Median age was 63 years with a median of 2 prior lines of therapy. No patient had achieved CR in any previous line of therapy, 67% were IMiD refractory and 56% were last line refractory (disease progression while on therapy). All patients were ongoing at the time of the data cut-off.

All 9 patients were still ongoing with a median treatment duration of 3.9 months. They received a total of 39 cycles of treatment with a median of 4.

Overall response rate								N/A*
	ORR	CR	VGPR	PR	MR	SD	PD	
total, N=9	86%	0	4	2	0	1	0	2

*2 of the 9 patients were still in their first cycle of treatment and were therefore not evaluable for response as described at time for data cut.

4 patients were treated with 30 mg melflufen and 5 patients were treated with 40 mg melflufen with no dose limiting toxicity observed. The combination of melflufen, dexamethasone and daratumumab was well tolerated with clinically manageable G3/4 hematological AEs and the low number of non-hematological AEs was noteworthy.

About Melflufen

Melflufen (Ygalo®), a peptide conjugated alkylator belonging to a novel class of peptidase-enhanced compounds, targets multiple myeloma (MM) cells with a unique mechanism of action. Aminopeptidases are enzymes found in all cells but are over-expressed in several cancers including MM. Ygalo® selectively targets MM cells through aminopeptidase-driven accumulation. In vitro experiments show a 50-fold enrichment of the active substance in MM cells compared with administration of equal amount of an alkylator not enriched by aminopeptidases. The enrichment results in selective cytotoxicity (increased on-target potency and decreased off-target toxicity), and that resistance pathways of existing myeloma treatments (including alkylators) is overcome. Melflufen also demonstrates strong anti-angiogenic properties.

Melflufen in clinical development

Melflufen (Ygalo®) has been used to treat late-stage RRMM patients in both phase I and phase II clinical studies (O-12-M1) with favorable results. Currently, melflufen is being studied in four clinical trials for the treatment of multiple myeloma. The current studies are OCEAN, HORIZON, ANCHOR and BRIDGE.

The current clinical study program is intended to demonstrate better results from treatment with melflufen compared to established alternative drugs for patients with multiple myeloma. Melflufen could potentially provide physicians with a new treatment option for patients suffering from this serious disease.

Melflufen 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 are ongoing with melflufen.

OCEAN is Oncopeptides pivotal Phase III study where melflufen 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 melflufen in late-stage RRMM patients with few or no remaining established treatment options. Updated interim data from this study will be presented at ASH in December 2018.

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

BRIDGE is a phase II study, where melflufen is used in RRMM patients with impaired renal function. This is a positioning study to show melflufen's treatment profile in these patients.

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 (Ygalo®), a peptide conjugated alkylator, belonging to a new class of drugs called Peptidase Enhanced Compounds. Melflufen is intended as an effective treatment of hematological cancers, and in particular multiple myeloma. The goal with the current clinical study program is to demonstrate better results from treatment with melflufen compared with established alternative drugs for patients with late-stage multiple myeloma. Melflufen will potentially provide physicians with a new treatment option for patients suffering from this serious disease.

Visit **www.oncopeptides.com** for more information.

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