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Balixafortide combination with eribulin in metastatic breast cancer data presented at ESMO 2018 show consistent positive trend for all efficacy endpoints, including overall survival

Polyphor presented new efficacy data on its immuno-oncology candidate, balixafortide, at the European Society for Medical Oncology (ESMO) 2018 Congress in Munich, Germany.

Final efficacy data of the Phase I study on the full expanded cohort of 24 patients were presented at an oral presentation, including the new overall survival analysis. Key findings included:

- For the expanded cohort population, the trial has shown a consistent positive trend for all the efficacy read-outs including overall response rate (ORR) of 37.5%, median progression free survival (PFS) of 6.2 months and median overall survival (OS) of 18 months. The data for eribulin alone in its registration trial for the USA ("EMBRACE")^{*} were 13%, 3.7 months and 13.1 months, respectively.
- Safety and tolerability of balixafortide + eribulin appeared comparable to published data on balixafortide or eribulin alone.
- These promising results suggest that balixafortide + eribulin might provide a new therapeutic option in heavily pre-treated metastatic breast cancer (MBC) patients and warrant further investigation in a randomized clinical trial.

Dr. Javier Cortes, Head of the Breast Cancer Program at IOB Institute of Oncology, Barcelona & Madrid and senior Investigator at Vall d'Hebron Institute of Oncology said: "This trial has shown the potential anti-tumor activity of a new class of agent, CXCR4 antagonist, in heavily pre-treated HER2 negative patients with metastatic breast cancer. The 6.2 months progression free survival and overall survival results of 18 months suggest the combination of balixafortide with eribulin has potential to provide a new therapeutic option for these patients in need and warrants further investigation in a Phase III trial as well as exploration of additional combinations of balixafortide with other anti-cancer therapies."

In addition, new preclinical data were presented in a poster session, where it was shown how balixafortide, after a substantial optimization process, represents the latest generation in CXCR4 antagonists with high potency and selectivity, strong receptor occupancy and a

^{*} "EMBRACE" registration trial for Eribulin

favourable ADME profile. Specifically, balixafortide showed superior potency in a panel of in vitro assays including receptor binding and occupancy, signaling pathways and chemotaxis.

About Balixafortide (POL6326)

Balixafortide is a potent and highly selective antagonist of CXCR4, a G-protein coupled receptor (GPCR) that regulates the trafficking and homing of both cancer cells and cells of the patient's immune system. CXCR4 plays a critical role in tumor growth, survival, angiogenesis and metastasisⁱ. High CXCR4 levels have been detected in almost all human tumor types, including breast cancer. High CXCR4 expression is known to correlate with aggressive metastatic behavior of cancer cells and a poor prognosisⁱⁱ.

Balixafortide is being developed to improve therapy outcomes in cancer, when used in combination with other agents. Balixafortide is the only CXCR4 antagonist in development for breast cancer and is the most advanced CXCR4 antagonist, being developed in solid tumors, being the first product candidate to reach proof of concept. The molecule was discovered based on Polyphor's proprietary macrocycle technology platform. Balixafortide showed strong results in a Phase Ib/proof of concept clinical trial in combination with eribulin in patients affected with advanced metastatic breast cancer. The development path identified with the input of the FDA is to conduct a single pivotal study to achieve approval in HER-2 negative metastatic breast cancer patients who previously received at least two chemotherapeutic regimens in the metastatic setting. Additionally, there is the possibility of achieving an accelerated conditional approval based on interim results. Polyphor is also conducting preclinical work to establish the potential for balixafortide in combination with other drugs and in other oncology indications.

About Polyphor

Polyphor is a clinical stage, Swiss biopharmaceutical company which has discovered and is developing the OMPTA (Outer Membrane Protein Targeting Antibiotics). The OMPTA are potentially the first new class of antibiotics against Gram-negative bacteria to have reached phase III stage in the last 50 years. The company's lead product, murepavadin, (POL7080) is in Phase III development against *Pseudomonas aeruginosa* – recognized as a critical priority 1 pathogen by WHO. Polyphor is also developing an immuno-oncology candidate, balixafortide (POL6326), which is in preparation for a pivotal trial program in combination with eribulin in patients with advanced breast cancer, and a pipeline of further preclinical antibiotics based on its OMPTA platform. Polyphor is based in Allschwil near Basel and is listed on the SIX Swiss Exchange (SIX: POLN). For more information, please visit www.polyphor.com.



Media Release

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ⁱ Otsuka S, Bebb G. *J Thorac Oncol.* 2008;3(12):1379-1383

ⁱⁱ Chatterjee S, Behnam Azad B, Nimmagadda S. *Adv Cancer Res.* 2014; 124:31-82