POLYPHOR

Media Release

Allschwil, Switzerland, March 9th, 2018

Polyphor announces successful end of Phase I meeting with FDA on its innovative immuno-oncology candidate balixafortide

Possibility of proceeding with a single pivotal trial to file for approval in the U.S. for combination with eribulin as third line therapy for metastatic breast cancer

Polyphor announced today the successful completion of its end of Phase I meeting with the U.S. Food and Drug Administration (FDA) for its novel immuno-oncology candidate balixafortide (POL6326), 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.

The FDA indicated that Polyphor could possibly proceed with a single pivotal trial to file for approval in the U.S. for the combination of balixafortide and eribulin (Halaven®) for treatment of patients with metastatic breast cancer who previously received at least two chemotherapeutic regimens. This could allow balixafortide to be approved in the U.S. for this indication by 2021, and possibly by the end of 2020 in case of accelerated approval based on interim data of Overall Response Rate (ORR) with an acceptable duration of response.

The FDA's advice on the development program was based on promising preliminary data shown in Polyphor's Phase I trial in which balixafortide was the first CXCR4 inhibitor to demonstrate proof of concept in solid tumors. Balixafortide combined with eribulin has shown a 63% Clinical Benefit Rate (CBR) and a 38% Overall Response Rate (ORR)[i]. The safety and tolerability of the combination appeared comparable to published data on either eribulin or balixafortide monotherapy.

Polyphor Ltd | Hegenheimermattweg 125 | 4123 Allschwil | Switzerland
T +41 61 567 16 00 | info@polyphor.com | www.polyphor.com

"This development significantly strengthens Polyphor's late-stage clinical pipeline and we now have two products entering the final stage of clinical development and with a clear path to market," said Giacomo Di Nepi, Chief Executive Officer of Polyphor. "Our highly constructive discussion with the FDA has resulted in specific next steps towards a pivotal trial to potentially support registration for balixafortide. We are grateful to the agency for its guidance and look forward to fully defining a development pathway to rapidly bring this new potential treatment option for women suffering from a disease that today still has poor prognosis and outcomes.

"We are also continuing to advance the Phase III program for our novel antibiotic, murepavadin, potentially the first representative of a new class against Gram-negative bacteria to enter Phase III in several decades."

"There is an ongoing need for novel treatments for patients with late stage HER2 negative breast cancers," said Dr. Javier Cortes, Head of the Breast Cancer Program at Ramon y Cajal University Hospital, Madrid and senior Investigator at Vall d'Hebron Institute of Oncology. "The preliminary anti-tumor activity and tolerability we have seen with balixafortide in combination with eribulin has been very encouraging and has potential to provide a new therapeutic option in these patients."

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 metastasis[ii]. 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 prognosis[iii].

In a clinical proof-of-concept trial in patients with advanced metastatic breast cancer, the combination of balixafortide with eribulin has shown a 63% Clinical Benefit Rate (CBR) and a 38% Overall Response Rate (ORR)[i]. In its registration trial for the USA ("EMBRACE" trial) eribulin alone showed a CBR of 28% and an ORR of 13%[iv]. In addition to its eribulin combination program for metastatic breast cancer, Polyphor is also conducting preclinical work to establish the potential for balixafortide in combination with other drugs and in other indications.

About Polyphor

Polyphor is a clinical stage, privately held Swiss specialty pharma 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 develop-ment against *Pseudomonas aeruginosa* – recognized as a critical priority 1 pathogen by WHO. Polyphor is also developing an immuno-oncology candidate, balixafortide (POL6326), cur-rently in Phase I / PoC for combination treatment in metastatic breast cancer, and a pipeline of further preclinical antibiotics based on its OMPTA platform. Polyphor is based in Allschwil near Basel. For more information, please visit www.polyphor.com.

For further information please contact:

Franziska Daabour
Communications
Polyphor Ltd.
Tel: +41 61 567 16 00
Email: PR@polyphor.com

For Investors:

Kalina Scott
Chief Financial Officer
Polyphor Ltd.
Tel: +41 61 567 16 67
Email: PR@polyphor.com

[i] Gil-Martin M. *et al.* Phase 1 study of the combination of balixafortide (CXCR4 inhibitor) and eribulin in HER2-negative metastatic breast cancer (MBC) patients. *J Clin Oncol.* 2017;35(15_suppl):2555-2555
[ii] Otsuka S, Bebb G. *J Thorac Oncol*. 2008;3(12):1379-1383
[iii] Chatterjee S, Behnam Azad B, Nimmagadda S. *Adv Cancer Res.* 2014; 124:31-82
[iv] "Embrace" registration trial for Eribulin