

Allschwil, Switzerland, May 17, 2019

## **Polyphor announces presentation of new survival data on balixafortide at the ASCO Annual Meeting 2019**

Polyphor AG (SIX: POLN) today announced that it will present new clinical data on survival outcomes of the Phase I trial of balixafortide, our lead immuno-oncology candidate, in combination with eribulin in HER2 negative metastatic breast cancer (MBC) at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago, May 31 – June 4, 2019.

The Phase Ib trial investigated balixafortide in combination with eribulin in 56 patients with advanced HER2 negative MBC. The overall survival for the expanded cohort was 50% at 18 months and 33.3% at 24 months, whereas the overall survival for the overall efficacy population was 42.4% at 18 months and 25% at 24 months. These data are consistent with the positive trend of all efficacy read-outs observed in this study and safety information is consistent with what was previously reported. Although inter-trial comparisons should be interpreted with caution, these survival rates, especially for the expanded cohort, are higher than those reported for eribulin monotherapy in similar MBC populations. These promising results suggest that balixafortide in combination with eribulin could potentially provide a new treatment option in heavily pre-treated patients with HER2 negative MBC.

The abstract will be presented during the session “Development Immunotherapy and Tumor Immunobiology”, on June 1, 8:00 AM – 11:00 AM:

**Abstract number and title:** #2606, poster Board: #250, “Balixafortide (a CXCR4 antagonist) + eribulin in HER2 negative metastatic breast cancer (MBC): survival outcomes of the Phase I trial”.

“We are pleased with the selection of our abstract for presentation at this year’s ASCO meeting. At the AACR Congress in April we already presented data derived from the analysis of patient samples and subsequent further studies confirming that balixafortide is a potent modulator of the immune system. Most breast cancer patients who received balixafortide showed a beneficial increase in the number of lymphocytes and neutrophils, cell types that have been both reported to support tumor cell elimination,” commented Frank Weber, Polyphor Director and a.i. Chief Medical and Development Officer. “The data presented further confirms the unique profile of balixafortide and its potential value in treatment of metastatic breast cancer – an area in which there is still a substantial unmet medical need.”

**For further information please contact:****For Investors:**

Kalina Scott  
Chief Financial Officer  
Polyphor Ltd.  
Tel: +41 61 567 16 67  
Email: [IR@polyphor.com](mailto:IR@polyphor.com)

**For Media:**

Alexandre Müller  
Dynamics Group AG  
Tel: +41 43 268 32 31  
Email: [amu@dynamicsgroup.ch](mailto:amu@dynamicsgroup.ch)

**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<sup>i</sup>. 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<sup>ii</sup>.

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 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 focused on the discovery and development of antibiotics and immuno-oncology compounds. It 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 OMPTA, murepavadin, (POL7080) is in Phase III development against *Pseudomonas aeruginosa* - recognized as a critical priority 1 pathogen by WHO; in addition, Polyphor is developing a pipeline of further preclinical antibiotics based on its OMPTA platform. In addition, Polyphor is developing an immuno-oncology candidate, balixafortide (POL6326), which is starting a Phase III trial in combination with eribulin in patients with advanced breast cancer, and exploring in parallel its potential for further combinations and indications. 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](http://www.polyphor.com).

**Disclaimer**

This press release contains forward-looking statements which are based on current assumptions and forecasts of the Polyphor management. Known and unknown risks, uncertainties, and other factors could lead to material differences between the forward-looking statements made here and the actual development, in particular Polyphor's results, financial situation, and performance. Readers are cautioned not to put undue reliance on forward-looking statements, which speak only of the date of this communication. Polyphor disclaims any intention or obligation to update and revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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

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