POLYPHOR

Media Release

Allschwil, Switzerland, February 20, 2020

Polyphor announces progress of the Phase III immuno-oncology program with balixafortide. Renewed strategy in advancing antibiotics and oncology research and pipeline

Polyphor AG (SIX: POLN), a research based clinical stage biopharmaceutical company, announces today progress of the Phase III immuno-oncology program with balixafortide and a renewed strategy in advancing antibiotics and oncology research and pipeline.

- **Polyphor to prioritize and continue executing the near term priority, Balixafortide Phase III program** - enrollment is progressing ahead of plan as a result of strong execution (192 patients, 50% total) and reaffirming timelines for achieving its first co-primary end point, ORR (Overall Response Rate).
- **Polyphor to set strategic priorities and the plan for its portfolio evolution beyond its major inflection point,** ORR results for balixafortide:
  - Given strong Phase III trial progress, complete the package for balixafortide potential MA (Marketing Authorization) filing and expanding its future opportunity.
  - Renewed strategy for developing innovative antibiotics with focus to formulation and peptide design optimization applying lessons learned from the murepavadin IV program, which the company has decided to terminate.
  - Advancing inhaled murepavadin for cystic fibrosis to Phase Ia in Q4 2020 after completion of the preclinical program suggesting broader (at least 5-10 times vs IV) safety margins.
  - Switch to a new formulation / new peptide design for POL7306 and not submit a CTA (Clinical Trial Application). Initiated a new target program within OMPTA class, thanatin derivatives.
  - A planned restructuring by up to 17 positions is expected to create operational efficiencies and help become a leaner and high-performance organization in delivering priorities.

Balixafortide Phase III Program:

- Polyphor's FORTRESS study, a pivotal Phase III study evaluating balixafortide (POL6326) in combination with eribulin for the treatment of patients with HER2 negative, locally recurrent or metastatic breast cancer (MBC), has randomized 192 (50%) patients to-date and enrollment is progressing ahead of plan.
- Completion of patient recruitment of 384 patients is expected for end of Q3 2020 and Polyphor reconfirms the data-cut for its first co-primary end point, ORR, by end of Q1 2021. ORR results could lead to an accelerated approval in the US after a potential breakthrough designation submission.
- Co-primary endpoint PFS (Progression Free Survival) is expected in Q4 2021 and will be the basis for a regular MA submission in the US and EU.
- If successful, balixafortide will be the first in class CXCR4 antagonist approved for a solid tumor indication widening the opportunities in the field of immuno-oncology.

Balixafortide Development Strategy:

- Polyphor plans to expand balixafortide into additional clinical studies to complete its package for a potential MA filing to capitalize on potential positive Phase III outcome, investigate additional dosing and scheduling options.
- Polyphor plans additional studies to enhance its characterization in CXCR4 driven immune pathway and pursue additional combinations in MBC.
- These studies are planned to be initiated starting from second half 2020 through 2021.

Oncology Research Expansion:

- Polyphor plans to expand research activities to further profile balixafortide activity in other combinations and tumors.
- Plans to identify additional novel development candidates in the field of immuno-oncology will be a strategic consideration moving forward.

- The company will actively pursue broadening academic and industry collaboration in the mid-term.

Antibiotics Research and Programs:

- Based on the thorough analysis of the learning from our research and development efforts, Polyphor will reprioritize remaining antibiotics programs with strong focus on formulation and peptide design optimization applying lessons learned from the murepavadin IV program, which the company has decided to terminate.
- Following the successful completion of the preclinical program suggesting at least 5-10 times higher safety margins versus IV formulation, Polyphor plans to submit CTA for inhaled murepavadin and start Phase Ia program in Q4 2020 for a future cystic fibrosis indication.
- Despite the promising efficacy package after completion of its preclinical program, the company will not submit a CTA for POL7306 program in 2020 due to estimated therapeutic margins. Polyphor plans to focus on a new formulation for POL7306 and peptide design optimization of its OMPTA BamA program to achieve broader therapeutic margins before moving into clinical trials.
- Polyphor initiated a new target program within OMPTA class, thanatin derivatives targeting specifically Enterobacteriaceae including multidrug resistant strains, one of the most common and resistant pathogens.
- Polyphor will continue research and development for the antibiotics pipeline with the support of existing and future non-dilutive and/or external financing.

Organization:

- In line with the renewed strategy, organization and resources will be focused on greatest opportunities innovation and value creation.
- A planned restructuring by up to 17 positions is expected to create operational efficiencies and help become a leaner and high-performance organization in progressing breakthrough science and innovation; consultation process with employees is initiated.

- New organization will be equipped to deliver balixafortide and inhaled murepavadin clinical studies while maintaining the core in research in antibiotics and oncology.
- Polyphor's Executive team consists of Gokhan Batur (CEO), Daniel Obrecht (CSO), Frank Weber (CMDO), Hernan Levett (CFO) and Franziska Muller (Head of HR) to lead the strategic transformation.

Financials:

- The company reconfirms its guidance that with existing cash, operations are financed until the end of Q1 2021.
- Under the current plan, the cash position will allow Polyphor to develop the balixafortide program towards the next value inflection point (ORR, around end of Q1 2021).
- Early stage antibiotics programs partly financed through non-dilutive funding and external financing. On-going discussions with key institutions in order to further support the antibiotics pipeline.
- Polyphor plans to release its FY 2019 financial results on April 28th 2020.

Business update conference call at 15.00 CET on 20 February 2020

Gökhan Batur (CEO), Hernan Levett (CFO), Daniel Obrecht (CSO) and Frank Weber (CMDO) will provide a business update, followed by a Q&A session.

Dial-in number:	**(CH)**	**+41 44 580 65 22**
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Conference-ID:	**41267291#**	

To follow the presentation, please use the below webcast link (no audio signal):
https://webcasts.eqs.com/polyphor20200220/no-audio

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About Polyphor

Polyphor is a research based clinical stage, Swiss biopharmaceutical company focused on the discovery and development of immuno-oncology compounds and a new class of antibiotics. Polyphor is advancing balixafortide (POL6326) in a Phase III trial in combination with eribulin in patients with advanced breast cancer, and exploring its potential in other cancer indications. In addition, it has discovered and is developing the Outer Membrane Protein Targeting Antibiotics (OMPTA). OMPTA are po-tentially the first new class of antibiotics in clinical development in the last 50 years against Gram-negative bacteria. The company's lead OMPTA program is an inhaled formulation of murepavadin for the treatment of Pseudomonas aeruginosa infections in patients with cystic fibrosis. 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.

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.