POLYPHOR

Media Release

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Polyphor announces positive Data Safety Monitoring Board (DSMB) recommendation to continue Phase III FORTRESS study without modifications

Polyphor AG (SIX: POLN) announced today that the Phase III clinical trial independent Data Safety Monitoring Board (DSMB) has completed the first, pre-specified interim analysis, of safety outcomes for the first 193 randomized patients in the Phase III pivotal study with balixafortide in HER2 negative, locally recurrent or metastatic breast cancer patients. The DSMB indicated that the Phase III clinical study should continue without modifications.

“As we continue to randomize new patients into the FORTRESS study and many patients continue on treatment, we are very pleased with the DSMB recommendation that the Phase III clinical trial continues without any protocol modification,” said Frank Weber, MD, CMDO of Polyphor. “We reaffirm the timeline to recruit 384 patients into FORTRESS by September 2020 and have randomized a total of 245 patients by today which is ahead of our plan. In the current situation with Covid 19 we are taking all possible measures to safeguard patients, investigators and the study conduct in general.”

FORTRESS (POL6326-009) is an international, multicenter, randomized active-controlled, open-label Phase III trial which will investigate the efficacy, safety and tolerability of intravenous balixafortide given with eribulin versus eribulin alone in the treatment of HER2 negative, locally recurrent or metastatic breast cancer. The study will comprise a total of 384 patients with HER2 negative MBC, of which 320 patients receiving third or subsequent line and 64 patients receiving second line chemotherapy. Subject to the data Polyphor will have the possibility to submit a filing for accelerated approval approximately six months after the recruitment is completed on the basis of the analysis of the overall response rate (ORR), confirmed by an independent blinded review, and of the associated durability of response. The full approval would be based on the magnitude of Progression Free Survival (PFS) on blinded independent review, supported by an overall survival trend favoring balixafortide arm and a favorable risk-benefit profile.

For more information about the POL6326-009 clinical trial of balixafortide, please visit www.clinicaltrials.gov (Identifier: NCT03786094)

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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

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