POLYPHOR

Media Release

Allschwil, Switzerland, May 9, 2019

Polyphor temporarily halts enrollment in the Phase III studies of murepavadin for the treatment of patients with nosocomial pneumonia

Polyphor (SIX: POLN) today announced the decision to temporarily halt enrollment for the pivotal Phase III trials PRISM-MDR and PRISM-UDR evaluating murepavadin in patients with nosocomial pneumonia due to higher than expected acute kidney injury incidences in the murepavadin arm of the PRISM-MDR trial. The kidney alteration incidences were observed in 56% of the patients treated in the PRISM-MDR study. According to literature and the comparator arm, an estimated incidence of 25-40% was expected. The decision has been taken consensually with the independent Data Monitoring Committee. An update on the continuation of both Phase III studies will be provided in July once all data will be available and reviewed.

“While pro-actively halting the Phase III trials for murepavadin is disappointing, patient safety is of utmost importance to Polyphor,” said Frank Weber, Polyphor Director and Chief Medical and Development Officer a.i. “We are trying to better understand the reasons for these events and exploring ideas on how to tackle them for the future, as we remain convinced that murepavadin could still represent a valuable drug to help patients fighting pseudomonas infections.”

The decision to temporarily halt enrollment applies only to the PRISM-MDR and PRISM-UDR studies and does neither impact the further development of the murepavadin inhaled program, nor the advancement of the OMPTA program, nor the development of the immuno-oncology candidate, balixafortide (POL6326), which is starting a Phase III trial in combination with eribulin in patients with advanced metastatic breast cancer.

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Polyphor will host a conference call at 08.00 CET on Friday, May 10, 2019. Giacomo Di Nepi (CEO) and Frank Weber (Director and CMDO a.i.) will provide an update on murepavadin, followed by a Q&A session.

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About the PRISM-MDR study
PRISM-MDR is a Phase III multicenter, open label, randomized, active-controlled, parallel-group study focused on hospitals where multidrug resistant strains of Pseudomonas aeruginosa are frequent. The study will compare murepavadin combined with one other anti-pseudomonal antibiotic against two other anti-pseudomonal antibiotics.

The study was designed based on feedback from the European Medicines Agency (EMA) and is agreed as the basis for a potential approval in the EU. The primary efficacy objective of the study is to assess the clinical cure rate at TOC in the mITT population. Eligible subjects with a high probability of VABP due to Pseudomonas aeruginosa will be randomized in a 2:1 ratio. The miTT population shall comprise 120 evaluable subjects (80 in the treatment arm) with VABP confirmed to be due to Pseudomonas aeruginosa.

About the PRISM-UDR study

PRISM-UDR is a global Phase III multicenter, sponsor blinded, randomized, active-controlled, parallel-group, non-inferiority study of murepavadin combined with ertapenem in adult patients with nosocomial pneumonia due to Pseudomonas aeruginosa. The primary efficacy objective is to demonstrate non-inferiority (20% non-inferiority margin) of murepavadin compared to an anti-pseudomonal β-lactam-based antibiotic. The study was designed based on feedback from the U.S. Food and Drug Administration (FDA) and is agreed as the basis for a potential approval in the US. Eligible subjects with a high probability of nosocomial pneumonia due to Pseudomonas aeruginosa will be allocated at random to receive murepavadin or a comparator beta-lactam agent in a 1:1 ratio. The primary analysis population will comprise 210 subjects (105 subjects per arm) with nosocomial pneumonia confirmed to be due to Pseudomonas aeruginosa.

About Murepavadin (POL7080)

Murepavadin is Polyphor's most advanced product candidate and the first OMPTA in clinical development. It is being developed for the treatment of nosocomial pneumonia (including both hospital-acquired (HABP) and ventilator-associated bacterial pneumonia (VABP)) due to Pseudomonas aeruginosa and has been granted Qualified Infectious Disease Product (QIDP) and fast track designation from the U.S. Food and Drug Administration (FDA) for the treatment of VABP due to Pseudomonas aeruginosa. Murepavadin is a pathogen specific antibiotic functioning through a novel mechanism of action involving binding to an outer membrane protein of Pseudomonas aeruginosa. In contrast to commonly used broad-spectrum antibiotics, murepavadin is a precision medicine and as such it supports the growing practice known as "antibiotic stewardship" which, among other things, seeks to reduce the excessive use of broad-spectrum products to avoid the buildup of resistance and to preserve the microbiome of the patients. Based on promising Phase II results, Polyphor has agreed on a streamlined development pathway for murepavadin with the FDA and EMA and has started its Phase III clinical program.

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.

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.