POLYPHOR

Media Release

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Polyphor announces protocol agreement with the FDA for the second pivotal Phase III study of murepavadin

Polyphor has started PRISM-UDR Phase III clinical trial of the pathogen-specific antibiotic murepavadin in patients with nosocomial pneumonia and expects to begin recruitment by Q119.

Polyphor announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) on protocol for its PRISM-UDR Phase III clinical study of murepavadin. The study has started with the first centers being enrolled. The study evaluates murepavadin for the treatment of nosocomial pneumonia due to Pseudomonas aeruginosa. Polyphor expects to recruit the first patient by Q119.

PRISM-UDR is a global Phase III multicenter, sponsor blinded, randomised, 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. With the agreed protocol, the FDA requested not to proceed with an interim analysis for the intention of stopping the trial early due to the small sample size. Therefore, the basis for a potential registration in the United States will be the completion of the single pivotal Phase III study, PRISM-UDR. 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 miTT population will comprise 210 evaluable subjects (105 subjects per arm) with nosocomial pneumonia confirmed to be due to *Pseudomonas aeruginosa*.

For more information about the PRISM-UDR clinical trial of murepavadin, please visit www.clinicaltrials.gov (Identifier: NCT03582007)

“Collaborating and reaching agreement with the FDA on the design of our pivotal trial for potential registration in the U.S. has been a priority for Polyphor. We are pleased to have reached this milestone as we are fully committed to the development of murepavadin that may lead to a paradigm shift in the treatment of nosocomial pneumonia due to Pseudomonas

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

aeruginosa," said Giacomo Di Nepi, Chief Executive Officer of Polyphor. "We now look forward to enrolling the first patients."

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 first Phase III clinical trial.

About Polyphor

Polyphor is a clinical stage, Swiss biopharmaceutical 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 development against Pseudomonas aeruginosa – recognized as a critical priority 1 pathogen by WHO. Polyphor is also developing an immuno-oncology candidate, balixafortide (POL6326), which is in preparation for a pivotal trial program in combination with eribulin in patients with advanced breast cancer, and a pipeline of further preclinical antibiotics based on its OMPTA platform. 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.

For further information please contact:

For Investors:

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

For Media:

Alexandre Müller
Dynamics Group AG
Tel: +41 43 268 32 31
Email: amu@dynamicsgroup.ch