
Polyphor and Roche join efforts to combat multidrug-resistant bacterial infections

Polyphor licenses investigational antibiotic POL7080 to Roche. POL7080 targets *Pseudomonas* species with a novel mode of action. This “superbug” bacterium is commonly found in hospitals and has evolved to become resistant to many antibiotic treatments.

Allschwil, Switzerland, November 4, 2013 - Polyphor Ltd, a privately held pharmaceutical company, and Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that they have entered into an exclusive worldwide license agreement to develop and commercialize Polyphor's investigational macrocycle antibiotic, POL7080, for patients suffering from bacterial infections caused by *Pseudomonas aeruginosa*.

Under the terms of the agreement, Roche will make an upfront payment of CHF 35 million to Polyphor as well as payments upon reaching certain development, regulatory and commercial milestones, potentially up to CHF 465 million. In addition, Polyphor is entitled to receive tiered double-digit royalties on product sales. Polyphor will retain the option to co-promote an inhaled formulation of POL7080 in Europe. The transaction is subject to customary regulatory clearances including termination of the applicable Hart-Scott-Rodino waiting period.

Antimicrobial resistance represents a major threat to public health worldwide, leading to 25,000 deaths and related costs of over €1.5 billion in healthcare expenses and productivity losses in the European Union alone each yearⁱ. *Pseudomonas aeruginosa* accounts for one in every 10 hospital-acquired infections in the USⁱⁱ and is listed as one of the six most dangerous drug-resistant microbesⁱⁱⁱ. Over 15% of *Pseudomonas aeruginosa* isolates were resistant to at least three classes of antibiotics and close to five percent were resistant to all five classes under surveillance^{iv}.

POL7080 belongs to a new class of antibiotics that kills *Pseudomonas aeruginosa* by a novel mode of action. It has demonstrated clinical safety and tolerability in a Phase I clinical trial and holds promise for the treatment of serious and often life-threatening bacterial infections caused by multi-drug resistant (MDR) *Pseudomonas* species.

“As part of our Infectious Diseases research strategy we focus on areas of high unmet medical need, where we feel we can make the most difference for patients. We are excited to partner with Polyphor as we build a portfolio of novel antibiotics,” commented Janet Hammond, Head of Infectious Diseases Discovery & Translational Area in Roche pRED. “As the incidence of drug-resistant infections is creating an urgent demand for new therapeutic options, we look forward to adding this potentially important, targeted agent with a novel mechanism of action to our portfolio of innovative medicines.”

“We are delighted about this license agreement. Roche is an ideal partner for POL7080, due to its long history of antibiotics development coupled with its strong scientific, clinical and commercial capabilities. This agreement is also an important milestone for Polyphor, as it is a further validation of our macrocycle technologies and rewards more than 10 years of research and development efforts. We are proud that Roche is building on our discovery and clinical results to bring this urgently needed product to patients as rapidly as possible,” said Jean-Pierre Obrecht, CEO and co-founder of Polyphor.

About antimicrobial resistance

Antimicrobial resistance represents a serious and growing threat to human and animal health worldwide. Resistance can also spread from animals to humans through the food chain or direct contact. According to the World Health Organization (WHO), 'antibiotic resistance is becoming a public health emergency of yet unknown proportions.' Meanwhile, new forms of resistance continue to arise and spread, leaving clinicians with few weapons to bring infections under control. Yet despite the recognized need for new antibiotics, the reality is that only two new classes of antibiotics have been brought to the market in the last three decades.^v

About *Pseudomonas* species

Pseudomonas is a bacterium commonly found in the environment which can give rise to serious, life-threatening infections in various types of tissue and usually occurs in patients in the hospital and/or with weakened immune systems. A significant proportion of Gram-negative infections are caused by *Pseudomonas* species.

Pseudomonas aeruginosa causes urinary tract infections, respiratory system infections, dermatitis, soft tissue infections, bacteremia, bone and joint infections, gastrointestinal infections and a variety of systemic infections. Any *Pseudomonas* infection represents a serious problem in immunosuppressed patients with cancer, AIDS and severe burns or in patients suffering from chronic infections such as Cystic Fibrosis. The case fatality rate in some of these patient groups is almost 50 percent.

Pseudomonas aeruginosa infections are generally treated with antibiotics. Unfortunately, in hospitalized patients, *Pseudomonas* infections, like those caused by many other hospital bacteria, are becoming more difficult to treat because of increasing antibiotic resistance.

About Polyphor

Polyphor is a Swiss Pharma company focusing on the discovery and development of macrocycle drugs addressing high unmet medical needs. Macrocycles represent a new drug class complementary to the classical small molecules and large biopharmaceuticals. Polyphor leverages its unique and proprietary technologies to develop its own product portfolio and to pursue licensing and collaboration opportunities. The company's lead drug candidates include POL6326, a CXCR4 antagonist, with ongoing and upcoming Phase II clinical trials for stem cell transplantation, tissue repair and combination treatments in oncology; POL7080, a highly specific antibiotic with a novel mode of action to treat *Pseudomonas* infections (Phase II initiated); and POL6014, an inhaled inhibitor of neutrophil elastase for the treatment of Alpha-1 Antitrypsin Deficiency, Cystic Fibrosis, and other lung diseases (ready for IND enabling studies). Polyphor is a privately held company with about 100 employees, headquartered in Allschwil, near Basel.

For additional information, please visit www.polyphor.com

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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Media contacts:

Polyphor Ltd

Michael Altorfer, Head Corporate Communications, Polyphor Ltd

Phone: +41 61 567 16 00

e-mail: PR@polyphor.com

Roche Group Media Relations

Alexander Klauser (Head), Silvia Dobry, Daniel Grotzky, Štěpán Kráčala

Phone: +41 61 688 88 88

e-mail: basel.mediaoffice@roche.com

ⁱ Source: ECDC/EMA joint technical report "The bacterial challenge: time to react," 2009

ⁱⁱ Source: US Center for Disease Control and Prevention

ⁱⁱⁱ Source: Infectious Diseases Society of America

^{iv} Source: ECDC "Antimicrobial resistance surveillance in Europe" 2011 report

^v Source: Innovative Medicines Initiative, *New IMI Projects to Revitalize Antibiotic Development*, 11 February 2013