INTRODUCTION

Antimicrobial resistance (AMR) is a growing problem worldwide, and with few new drugs making it to the market, there is an urgent need for new medicines to manage infections caused by resistant pathogens. In this respect, most troublesome is the rapid emergence and dissemination of multidrug resistant (MDR) bacteria. There is an unmet medical need to prevent respiratory tract infections caused by the bacterium Pseudomonas aeruginosa in critically ill patients and to develop new antibiotics for infections caused by MDR-GNB (Gram-negative bacteria) including, but not limited to urinary tract and intra-abdominal infections. Efforts to develop novel antibiotics are hampered by a number of scientific and regulatory hurdles that cannot be easily tackled by any individual organization working alone.

If no action is taken to address these issues, we risk leaving society in a situation where doctors will have few, if any, options to treat bacterial infections. To avoid a public health emergency, the entire antibiotic research community must work together to reinvigorate research into new antibiotics.

COMBACTE-MAGNET

COMBACTE MAGNET is a new, highly innovative research programme in which academic and industrial partners are collaborating to combat the threat of antibiotic resistance for patients worldwide. The COMBACTE-MAGNET project is investigating a new approach for preventing respiratory infections in ICU patients and new treatment options for patients with life-threatening infections due to MDR-GNB. The project will deliver groundbreaking multinational phase 2 and 3 studies in intensive care unit patients with MDR-GNB, MedImmune’s monoclonal antibody being investigated for the prevention of nosocomial pneumonia caused by a highly drug resistant bacterium, Pseudomonas aeruginosa. In addition, a Phase 1 study will be conducted with MED3902 in paediatric patients at risk of P. aeruginosa infections. In September 2014, the US Food & Drug Administration granted Fast Track designation to MED3902. The Phase 2 EVADE study designed by the consortium to evaluate the efficacy and safety of MED3902 in ICU patients at risk for developing P. aeruginosa pneumonia is now open for enrolment (ClinicalTrials.gov Identifier: NCT02696902). Current status of the study: 36 active sites with 158 patients screened of which 33 patients were enrolled.

The consortium will perform phase 1 and phase 2 studies, including extensive pharmacokinetic/pharmacodynamic studies, with a new beta-lactam antibiotic from Acumin - AIC499 - with enhanced beta-lactamase stability and efficacy against a broad range of MDR-GNB, including P. aeruginosa and Acinetobacter species. Alone, or in combination with a beta-lactamase inhibitor (BLI), AIC499 is active against MDR isolates producing a wide range of beta-lactamases, and therefore, offers the real prospect of a new treatment option for patients with life-threatening infections due to MDR-GNB.

Current status of the study: The first phase I study is in progress.

The RESCUEING study is a retrospective observational study to assess the clinical management and treatment outcomes of hospitalized patients with complicated urinary tract infections, in countries with a high prevalence of multidrug resistant Gram-negative bacteria including Bulgaria, Greece, Hungary, Israel, Italy, Romania, Turkey, and Spain. Current status of the study: Data collection of 1,013 patient dosiers was completed. Analysis report in progress. First publication on study protocol accepted for publication.

FACTSHEET

The Innovative Medicines Initiative (IMI) New Drugs 4 Bad Bugs programme represents an unprecedented partnership between industry and academia to combat antibiotic resistance in Europe. Antibiotic-resistant bacteria cause approximately 25,000 deaths in the EU, with two thirds of these deaths due to Gram-negative bacteria and costing the European economy an estimated €1.5 billion per year. The €167 million COMBACTE-MAGNET project aims - during the 7-year project term - to create new approaches in clinical research and to develop two innovative antibacterial molecules to address antibacterial resistance against the most problematic of drug-resistant pathogens, the Gram-negative bacteria.

COMBACTE-MAGNET GOVERNANCE STRUCTURE

COMBACTE MAGNET will closely collaborate with and further strengthen the clinical and laboratory networks of COMBACTE, the first project within the N4DR programme that started in January 2013. Furthermore, a pan-European collaboration is being created (called EPI-Net) within COMBACTE-MAGNET to map and utilize available surveillance systems in Europe in order to optimally describe the epidemiology of antibiotic resistance and healthcare associated infections.

CONTACT INFORMATION

Unique in its scale, ambition, and its potential benefits for patients, public health and pharmaceutical research in Europe, COMBACTE has the potential to become the powerhouse of anti-microbial drug development in Europe that could serve as a standard for other groups. Join us!

Visit us at booth 29 in the exhibition hall.

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