COMBACTE-MAGNET

Combatting Bacterial Resistance in Europe - Molecules against Gram-Negative Infections

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 MEDI3902, 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 MEDI3902 in paediatric patients at risk of *P. aeruginosa* infections. In September 2014, the US Food & Drug Administration granted Fast Track designation to MEDI3902. The Phase 2 EVADE study designed by the consortium to evaluate the efficacy and safety of MEDI3902 in ICU patients at risk for developing *P. aeruginosa* pneumonia is now open for enrolment (ClinicalTrials.gov Identifier: NCT02696902).

The consortium will perform phase 1 and phase 2 studies, including extensive pharmacokinetic /pharmacodynamic studies, with a new beta-lactam antibiotic from AiCuris - 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-GNBs.

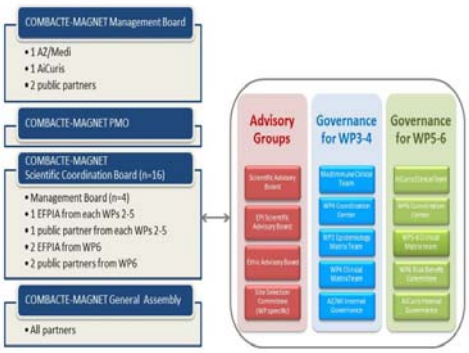
The RESCUING study is a retrospective observational study is currently enrolling to assess the clinical management and treatment outcomes of hospitalized patients with complicated urinary tract infections, in countries with a high prevalence of multidrug resistant Gram-negative bacteria including Bulgaria, Greece, Hungary, Israel, Italy, Romania, Turkey, and Spain.

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 time - 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



COLLABORATION

The COMBACTE-MAGNET consortium brings together 5 pharmaceutical industry partners and 33 academic partners, and is a true nexus of world class researchers from 7 European countries with expertise in the field of antibiotic resistance. The two European Federation of Pharmaceutical Industries and Associations (EFPIA) project sponsors, MedImmune, the global biologics research and development arm of AstraZeneca, along with AiCuris, will provide their novel, investigational infectious disease molecules MEDI3902 and AIC499 in addition to their study-related expertise.

COMBACTE

COMBACTE-MAGNET will closely collaborate with and further strengthen the clinical and laboratory networks of COMBACTE, the first project within the ND4BB 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 37A in the exhibition hall.

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ND4BB COMBACTE

This research project receives support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115523 | 115620 | 115737 resources of which are composed of financial contribution from the European Union Seventh Framework Programme (FP7/2007-2013) and EFPIA companies in kind contribution.