COMBATEC
COMBATTING BACTERIAL RESISTANCE IN EUROPE

COMBACTE-CARE
COMBACTE-CARE (Combating Bacterial Resistance in Europe-Carbenem Resistant) aims to improve our knowledge on clinical management and outcomes of hospitalized patients with Carbapenem Resistant Enterobacteriaceae (CRE) infections. To analyse clinical and microbiological data to provide new insights for novel clinical trial design and to make recommendations for the development of novel antibiotics to treat resistant infections.

The EFPIA coordinator role on this project will transition from AstraZeneca to Pfizer following the divestment of the AstraZeneca antibiotic portfolio, including ATM-AVI, to Pfizer

CLINICAL TRIALS
When COMBACTE-CARE the following clinical trials are currently active:

EUREGA: A prospective observational study to assess the clinical management of patients with infections caused by CRE or carbapenem-resistant Acinetobacter. It will be supported by an already operational cohort for the identification of biomarkers in critically ill patients.

(STATUS: 31 of 40 selected sites actively recruiting. 406 patients of 2,000 patient target enrolled in study cohort)

REJUVENATE: A PK/PD trial to evaluate the pharmacokinetics and safety of the combination drug Astrazenema-Avibactam (ATM-AVI) in patients with complicated intra-abdominal infections. ATM-AVI was developed by AstraZeneca.

(STATUS: 21 patients of 40 patient target have been enrolled in the study)

COMBACTE-CARE will also provide medical leadership and support to European sites to a global. Phase III clinical trial designed to evaluate the safety and efficacy of ATM-AVI for the treatment of serious infections with Gram-negative bacteria resistant to other antibiotics but are susceptible to this combination.

This clinical trial is also additionally funded outside Europe by the US Biomedical Advanced Research and Development Authority (BARDA) and has been supported by an agreement between AstraZeneca and BARDA. This agreement is currently subject to transition to Pfizer

CONTACT INFORMATION
Visit us at booth 29 in the exhibition hall.
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COMBACTE-NET
COMBACTE-NET aims to establish a high-quality, pan-European network of clinical sites, that will form the backbone for clinical studies within the wider NO4ABB program.

Next to the clinical - and research site network CLIN-Net, COMBACTE-NET contains three networks:

CLIN-Net
A network of hospitals capable of efficiently recruiting, treating, monitoring and reporting data on the required number of patients in clinical, multicenter trials at all stages of clinical drug development.

LAB-Net
A network of microbiology laboratories delivering high-quality and standardized information on microbial strains and antibiotic resistance and providing microbiological diagnostic support needed for the execution of such trials.

STAT-Net
A network of academic and industry experts in the area of clinical trial design to optimize the design of Phase II and Phase III clinical trials based on advanced statistical and pharmacological modeling and innovative biostatistical and epidemiological concepts.

CLINICAL TRIALS
Within COMBACTE-NET the following clinical trials are currently active:

SAATELLITE: A Phase II study to evaluate the effectiveness of MEDIX902, a monoclonal antibody against aflatoxin in S. aureus, in preventing S. aureus HAP/VAP in ICU patients. MEDIX902 was developed by Medimmune.

(STATUS: 44 active sites enrolling patients. 463 patients have been screened of which 135 were enrolled.)

ASPIRE-ICU: A prospective, observational, epidemiologic cohort study of ICU patients with healthcare associated infections caused by S. aureus or other Gram-positive or Gram-negative pathogens.

(STATUS: 27 active sites, enrolling patients in 15 sites. 3,226 patients are in the surveillance population. 487 patients of the 2,000 patient target are in the study cohort population.)

ASPIRE-SSI: A prospective, observational, epidemiologic cohort study of patients undergoing surgery to determine the incidence of S. aureus surgical site infections (SSI).

(STATUS: First sites are active. 5 patients screened of which 2 have been enrolled. Target is 5,000 patients in the study cohort.)

ANTICIPATE: a prospective observational cohort study of patients receiving antibiotic treatment during hospitalization to estimate the incidence of Clostridium difficile infections (CDI), antibiotic-associated diarrhea (AAD), and changes in the diversity and composition of the intestinal microbiota.

(STATUS: enrolling patients at 33 sites)

COMBACTE-MAGNET
COMBACTE-MAGNET (Combating Bacterial Resistance in Europe - Molecules against Gram-negative Infections) aims to improve our knowledge on the biological markers of P. aeruginosa infections, transmission dynamics of these bacteria, and on the host-specific response of individuals. Such knowledge will enable researchers to design more efficient and effective clinical trials of new molecules.

COMBACTE-MAGNET contains one European network:

EPI-Net
A network to harmonise and connect various European systems of disease surveillance by linking clinical, microbiological, and public health data.

CLINICAL TRIALS
Within COMBACTE-MAGNET the following clinical trials are currently active or completed:

EVADE: To determine the efficacy of MEDIX902, a bispecific monoclonal antibody that inhibits two key virulence factors of P. aeruginosa (PorA and Psl) in preventing P. aeruginosa HAP/VAP. MEDIX902 was developed by Medimmune, as a new way of preventing pulmonary P. aeruginosa infections without using antibiotics.

(STATUS: 30 active sites with 158 patients screened of which 33 patients were enrolled)

RESCURING: 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 multiresistant Gram-negative bacteria, including Bulgaria, Greece, Hungary, Israel, Italy, Romania, Turkey, and Spain.

(STATUS: Data collection of 1,013 patient dossiers was completed. Analysis report in progress. First publication on study protocol accepted for publication)

AIC949: a new and potent member of the family of so-called beta-lactamase inhibiting drug (BLI). AIC949 has shown strong activity against a broad range of multidrug-resistant strains of P. aeruginosa and Acinetobacter, both in laboratory and animal studies. AIC949 is being developed by AICuts.

(STATUS: The first phase I study is in progress)