



## **Press release**

**University Medical Center Utrecht on behalf of COMBACTE-CARE\***

### **COMBACTE-CARE: A NEW PUBLIC-PRIVATE FUNDED PROJECT TO COMBAT CARBAPENEM RESISTANCE**

**Utrecht (the Netherlands), March 25, 2015** – Today 18 European academic partners and 3 pharmaceutical companies are launching a new project under the Innovative Medicines Initiative (IMI) funded New Drugs 4 Bad Bugs (ND4BB) program: COMBACTE-CARE. COMBACTE-CARE (Combatting Bacterial resistance in Europe-Carbapenem-Resistance) will bring highly innovative studies and activities related to the treatment of patients with infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE). Being very difficult to treat and sometimes deadly, CRE are considered to be one of the most dangerous resistant bacteria in the world. University Medical Center Utrecht is the project's managing entity.

Antibiotic resistance is a global public health threat and infections due to multi-drug resistant Gram-negative bacteria (MDR-GNB) are rapidly increasing. Especially infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE) are of major concern. The US Centers for Disease Control and Prevention recently concluded that CRE represent an immediate public health threat that requires urgent and aggressive action. CRE expresses resistance to most available antibiotics, leaving few available options for therapy. New treatments are therefore urgently needed. In addition, the epidemiology of CRE is characterized by large heterogeneity in genotypes and phenotypes, seriously hampering the rapid detection of CRE.

The EUR 83 million COMBACTE-CARE projects aims – during the 5-year project time - to understand how patients with CRE infections are managed, with a focus on best available treatment and clinical outcomes. The project will develop new tools to detect CRE and conduct clinical trials with AstraZeneca's antibiotic combination product Aztreonam-Avibactam (ATM-AVI), in development for the treatment of serious infections due to metallo- $\beta$ -lactamase producing Gram-negative pathogens, a difficult to treat sub-type of CRE infections.

Professor Marc Bonten, University Medical Center Utrecht: "*COMBACTE-CARE will be the first concerted action in the ND4BB program to combat the rapidly growing threat of infections caused by carbapenamase-producing bacteria in Europe.*"

Concrete activities of the COMBACTE-CARE consortium include:

1. Prospective observational studies to assess the risk factors, clinical management and outcomes of hospitalized patients with serious infections caused by MDR-GNB;
2. Microbiological studies to support the prospective observational, phase II and phase III studies;
3. Biomarker studies to optimize patient selection with poor outcome in future studies;
4. A Phase II prospective, multicenter study, to determine the pharmacokinetics (PK), safety and tolerability of ATM-AVI for the treatment of complicated Intra-abdominal Infections (cIAIs) in hospitalized adults;
5. European component of a prospective, randomized, multicenter, assessor-blind, parallel group, comparative Phase III study to determine the efficacy, safety and tolerability of ATM-AVI for the treatment of serious infections due to metallo- $\beta$ -lactamase producing Gram-negative pathogens.

All clinical and microbiological studies will be conducted in South-Eastern Europe, where infection rates with MDR-GNB are expected to be high. The phase III study is intended to include investigation sites outside Europe to ensure the global assessment of the ATI-AVI combination product.

Dr Seamus O'Brien, EFPIA Coordinator, AstraZeneca: *"This unique collaboration addresses the need for greater understanding of the clinical management and outcomes of CRE infections and also makes a significant contribution to the development of Aztreonam-avibactam for the treatment of patients with serious infections caused by Gram-negative bacteria for which currently there are limited or no treatment options."*

The COMBACTE-CARE project will closely collaborate with and further strengthen the clinical and laboratory networks CLIN-Net and LAB-Net of COMBACTE, one of the first projects within the ND4BB program, that started in January 2013.

Efforts to develop novel antibiotics are hampered by a number of scientific and regulatory hurdles that cannot be easily tackled by any individual organization. The COMBACTE-CARE consortium brings together 18 European academic partners, 3 European Federation of Pharmaceutical Industries and Associations (EFPIA) partners from 10 European countries to closely collaborate on combatting Carbapenem resistance. COMBACTE-CARE researchers are widely considered to be global opinion leaders due to their expertise in executing clinical trials evaluating new (and established) antibiotics or anti-infective agents, antibiotic strategies and preventive measures against Healthcare-associated Infections (HAIs) as well as guiding antibiotic and infection prevention policies.

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### Note to the editor

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### About University Medical Center Utrecht

University Medical Center Utrecht (UMC Utrecht) belongs to the largest public healthcare institutions in the Netherlands. It was created in 2000 through the merger of Utrecht Academic Hospital, Wilhelmina Children's Hospital and the Medical Faculty of Utrecht University. UMC Utrecht has the ambition to be a leading international healthcare provider, medical school and research institute that is exciting for its people, attractive to talent and embodies a culture of teamwork, innovation, sustainability and high performance. As a patient-centered organization, its 11,000 employees are dedicated to prevent disease, improve healthcare, develop new treatment methods and refine existing ones, with patient safety and quality as cornerstones. Strategic research programs are Brain, Child Health, Circulatory Health, Infection & Immunity, Personalized Cancer Care and Regenerative Medicine & Stem Cells. UMC Utrecht is embedded in a vibrant and entrepreneurial science community where knowledge about health, disease and healthcare is generated, validated, shared and applied. For more information, visit [www.umcutrecht.nl](http://www.umcutrecht.nl) or follow us on Twitter @UMCU\_INTL.

### About IMI ND4BB program

Antibiotic-resistant bacteria kill 25 000 people in the EU every year, and cost the economy €1.5 billion. Innovative Medicines Initiative (IMI) New Drugs 4 Bad Bugs (ND4BB) program has been launched to stimulate antibiotic development in Europe. ND4BB represents an unprecedented partnership between industry, academia and biotech organizations to combat antibiotic resistance in Europe by tackling the scientific, regulatory, and business challenges that are hampering the development of new antibiotics. For more information on COMBACTE-CARE, visit [www.combacte.com](http://www.combacte.com). For more information on IMI, visit [www.imi.europe.com](http://www.imi.europe.com)

### \* Participants COMBACTE-CARE

Universities, research organizations, public bodies, non-profit groups:

UMC Utrecht, The Netherlands; Université de Geneve, Switzerland; CHU Limoges, France; Servicio Andaluz de Salud, Spain; Universitätsklinikum Köln, AöR (University Hospital of Cologne), Germany; Tel-Aviv Souraski Medical Center, Israel; National and Kapodistrian University of Athens, Greece; INSERM, France; St. Georges University London, UK; University Clinical Center Kosova, Kosovo; UMC Groningen, The Netherlands; Tel Aviv University, Israel; Cardiff University, UK; Servicio Madrileño de Salud - Hospital Universitario Ramón y Cajal, Spain; University of Barcelona, Spain; Academisch Medisch Centrum, The Netherlands; University Antwerp, Belgium; Universität Ulm, Germany

EFPIA companies:

AstraZeneca, UK; GlaxoSmithKline, UK; Basilea, Switzerland