



Antibacterial Resistance Leadership Group joins the COMBACTE/MedImmune programs bringing US expertise and US clinical sites

Utrecht (the Netherlands), February 23, 2018 – The Antibacterial Resistance Leadership Group (ARLG), funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health, becomes the first US consortium to join the ongoing MedImmune Phase II programs being conducted within the COMBACTE (Combatting Bacterial Resistance in Europe) consortium, bringing US-focused expertise and clinical sites to the programs. MedImmune is the global biologics research and development arm of AstraZeneca and is developing monoclonal antibodies to prevent serious bacterial diseases without contributing to antimicrobial resistance. The COMBACTE projects are supported by the Innovative Medicines Initiative, a public-private partnership between the European Union and the pharmaceutical industry.

The first Phase II program includes the ongoing SAATELLITE study ([NCT02296320](#)), which is evaluating suvatroxumab (previously known as MEDI4893) in mechanically ventilated intubated ICU subjects for prevention of *Staphylococcus aureus* pneumonia. The study is the first interventional trial designed and executed within COMBACTE, and is led by Dr. Hasan Jafri from MedImmune and Dr. Bruno François from Limoges University Hospital in France.

The second Phase II program includes the ongoing EVADE study ([NCT02696902](#)), which is evaluating MEDI3902 in mechanically ventilated intubated ICU subjects for prevention of *Pseudomonas aeruginosa* pneumonia. The study is led by Dr. Hasan Jafri and Prof. Jean Chastre from the Paris Hospital (Groupe Hospitalier Pitié-Salpêtrière).

The ARLG collaboration is headed by Dr. Vance Fowler and Dr. Henry F. Chambers and facilitated by the Duke Clinical Research Institute (DCRI), which is funded by NIAID under grant number UM1AI104681. Dr. Thomas Holland is the US Coordinating Physician for the studies. Through ARLG, the SAATELLITE and EVADE programs have access to approximately 15 US sites as well as US expertise. The first US site, located in Detroit MI, was activated in January 2018. This is a major milestone for the COMBACTE program and it clearly demonstrates the benefits of public-private collaboration and international collaboration between COMBACTE and ARLG.

Dr. Thomas Holland of ARLG remarked: “The collaboration is a good fit. The EVADE and SAATELLITE trials seek to prevent ventilator-associated pneumonia caused by *Staphylococcus aureus* and *Pseudomonas aeruginosa*. The ARLG is charged with advancing clinical trials that address the public health threat of antibacterial resistance. This collaboration and others like it will enable us to evaluate a promising approach to the prevention of difficult-to-treat and difficult-to-study infections in intensive care units.”

Commenting on COMBACTE, Bruno François, academic coordinating principal investigator of the SAATELLITE study, said: “COMBACTE’s main objective is to deliver clinical trials, testing new drugs through a new collaborative approach between pharmaceutical companies and academics. It also aims to bring capability building in the infectious disease field, not only at the European level but also worldwide. COMBACTE is developing different networks in addition to the existing ones, such as CLIN-Net to identify the best European investigation sites for infectious disease research, fully complementary to LAB-Net, which aims to regroup the laboratories with a research expertise, and a network with strong methodological expertise (STAT-Net). Collaborating with the ARLG will open up this capability building towards the US. Working with US experts in the field, as well as activating additional sites in the US, will help reach the goals



set forth for the EVADE and SAATELLITE programs."

Hasan Jafri, EFPIA (industry) lead for the SAATELLITE and EVADE studies, Senior Director, Clinical Development, Infectious Disease & Vaccines at MedImmune added: "An increase in emergence of antimicrobial resistance combined with a steady decline in the number of novel antimicrobials being developed has significantly limited treatment options for diseases caused by pathogen-specific infections. Novel biologics under investigation, such as suvratumab and MEDI3902, may offer a unique opportunity to help prevent these serious infections without inducing antimicrobial resistance. We believe collaboration with world-renowned experts, such as those within COMBACTE and the ARLG, is one of the best models to advance development in this area, and bring novel and effective anti-infectives to patients."

-ENDS-

Notes to editors:

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About IMI ND4BB program

Innovative Medicines Initiative (IMI) New Drugs 4 Bad Bugs (ND4BB) program has been launched by the European Union and the European Federation of Pharmaceutical Industries and associations (EFPIA). It 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. All COMBACTE projects are included within this IMI ND4BB program. For more information on the COMBACTE projects, visit www.combacte.com. For more information on IMI, visit www.imi.europa.eu

About COMBACTE

In November 2011, the European Commission, as part of its action plan to combat the increasing threat of antimicrobial resistance, called for "unprecedented collaborative research and development effort to bring new antibiotics to patients," including the launch of the sixth, the eighth and the eleventh IMI Calls for Proposals in May 2012, December 2012 and December 2013 respectively, as part of the program entitled "New Drugs 4 Bad Bugs (ND4BB)." Within the ND4BB program are the COMBACTE-NET, COMBACTE-MAGNET, COMBACTE-CARE, and COMBACTE-CDI consortia, which were formed in January 2013, January 2015, March 2015, and November 2017, respectively.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca.com and follow us on Twitter @AstraZeneca.

About the ARLG

The Antibacterial Resistance Leadership Group (ARLG) develops, designs, implements, and manages a clinical research agenda to increase knowledge of antibacterial resistance. The ARLG aims to advance research by building transformational trials that will change clinical practice and reduce the impact of antibacterial resistance. The ARLG is facilitated by the Duke Clinical Research Institute (DCRI) and works under the centralized leadership of an Executive Committee and two Principal Investigators (PIs). Dr. Vance Fowler, Duke University, and Dr. Henry F. Chambers, UCSF. For more information visit www.arlg.org



About University Medical Center Utrecht

University Medical Center Utrecht hosts the COMBACTE program office and belongs to the largest public healthcare institutions in the Netherlands. It is an internationally leading 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 a competitive spirit. 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 quality and patient safety as cornerstones. For more information, visit www.umcutrecht.nl.