



Press Release

Completion of the first interventional Phase-II trial in the Innovative Medicines Initiative's COMBACTE-NET Consortium

Results from the SAATELLITE trial to be presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) and American Thoracic Society (ATS) meetings by the COMBACTE-NET Consortium

April 11, 2019 – The Innovative Medicines Initiative (IMI)-funded COMBACTE-NET (*Combatting Bacterial Resistance in Europe*) consortium has completed the SAATELLITE study, a phase II trial of suvratoxumab, a novel monoclonal antibody (mAb) targeting *Staphylococcus aureus*. The trial, sponsored by AstraZeneca and part of the Innovative Medicines Initiative (IMI) programme, assessed the novel mAb's ability to prevent *Staphylococcus aureus* Ventilator-Associated Pneumonia (VAP) in mechanically ventilated intensive care unit (ICU) patients.

The trial forms part of the New Drugs 4 Bad Bugs (ND4BB) programme, launched by the IMI, which aims to address the challenges of rising antimicrobial resistance (AMR) in Europe. SAATELLITE is the first clinical trial testing an innovative anti-infective drug outside antibiotics in the ND4BB framework and its completion is an important milestone for the programme.

Within the ND4BB programme, the [COMBACTE-NET consortium](#) represents the first European public-private partnership established to promote the clinical development of new medicines in the fight against AMR. The diverse group of experts comprising the consortium membership specialise in microbiology, critical care, epidemiology, biomarkers, or management of clinical trials from research bodies, universities, hospitals, as well as pharmaceutical companies, providing a unique opportunity to improve and accelerate the development of anti-infectives.

An objective of COMBACTE-NET was to support the clinical development of suvratoxumab (MEDI4893), a human mAb, developed by AstraZeneca that targets a toxin produced by *Staphylococcus aureus*, which is one of the leading bacteria often associated with hospital-associated infections and linked to AMR.

The Phase 2 trial, [SAATELLITE](#), was led by Bruno François from Limoges University Hospital (France) as Coordinating Principal Investigator, and Hasan Jafri from AstraZeneca as the industry scientific lead. It is the first interventional trial to be designed and executed within COMBACTE-NET. It also represents a potential paradigm shift in the infectious disease field, studying a pre-emptive approach using a mAb to prevent VAP and nosocomial pneumonia due to *Staphylococcus aureus* in critically ill patients in the ICU. Patients were eligible if they were colonised in the lower respiratory tract with *Staphylococcus aureus*; determined by using a real-time polymerase chain reaction (PCR) assay, another innovative approach of the trial.

Hasan Jafri, Senior Director of Clinical Research and Development, AstraZeneca, and Coordinator of COMBACTE-NET, said: "The SAATELLITE study is an example of a highly successful public-private collaboration, necessary for the development of novel medicines to address the challenges of rising



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antimicrobial resistance in Europe. As the first and largest pre-emptive trial within the consortium, the novel trial design required the development of novel endpoints, which set SAATELLITE apart from the traditional non-inferiority trials of antibiotics.”

Bruno Francois, the Coordinating Principal Investigator from Limoges University Hospital, said: “The SAATELLITE trial definitely demonstrates the extraordinary capability of the COMBACTE-NET consortium to set up and execute such a novel trial in an ICU patient population. SAATELLITE has opened the field of infection prevention using monoclonal antibodies. Based on the lessons learned and taking benefit of the different COMBACTE resources, a similar phase II trial using another mAb targeting *Pseudomonas aeruginosa* in mechanically ventilated patients is currently recruiting within the COMBACTE-MAGNET consortium.”

Pierre Meulien, Executive Director, IMI, said: “Public-private collaboration is essential if we are to make progress on the development of new treatments for resistant infections. The successful completion of the SAATELLITE study is the result of a lot of hard work by scientists from academia and industry, as well as countless clinicians, across Europe. I would also like to thank the patients who agreed to be part of this ground-breaking study.”

SAATELLITE topline results are being presented at the [ECCMID meeting](#) in Amsterdam on April 16th and at the [ATS meeting](#) in Dallas on May 20th.

Notes to Editors:

About the SAATELLITE trial

The SAATELLITE trial introduced new concepts in clinical research with a pre-emptive approach and the use of PCR molecular diagnostics for screening patients for study eligibility. The SAATELLITE study had broad and very active participation from all stakeholders, exemplifying the public-private partnership. These include: development of the protocol including endpoint definitions; developing transparent prespecified criteria for selection of research centers and clinical research organizations (CRO); and independent academic committees providing scientific, safety, and operational oversight. Networks within COMBACTE-NET, such as CLIN-Net and LAB-Net were involved in the selection and training of sites and laboratories. CLIN-Net maintains an up-to-date portfolio of clinical trial sites across Europe. This maximizes the efficiency of site selection and study performance for studies related to antimicrobial resistance. LAB-Net also coordinated the biomarker analyses across the various specialty academic biomarker laboratories in Europe. Study subjects were screened at 48 research hospitals across 9 countries in Europe.

About the IMI ND4BB Program

Innovative Medicines Initiative (IMI) New Drugs 4 Bad Bugs (ND4BB) programme has been launched by the European Union, represented by the European Commission 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 through funding by the EU and Innovative Medicines Initiative, and in-kind contributions from the EFPIA. For more information on the COMBACTE projects, visit www.combacte.com. For more information on the IMI ND4BB programme visit <https://www.imi.europa.eu/projects-results/project-factsheets/nd4bb> www.imi.europa.eu and on IMI visit www.imi.europa.eu.

About Limoges University Hospital

Limoges University Hospital was created in 1976 with three main missions: patient care, teaching and research & innovation. CHUL is made up of 5 different hospitals with more than 7,000 professionals and one Inserm-certified Clinical Investigational Center (IC 1435) which gathers more than 40 people (physicians, European project managers, study nurses, clinical research assistants, financial officers, medical translators, etc.). The IC 1435 is dedicated to the promotion and implementation of clinical research within and outside the Limoges Hospital. In addition to multicenter research projects



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participation and logistical support to local teams, the CIC strongly focuses its research activities on infectious diseases including antibiotic resistance mechanism, and infectious disease in critically ill patients. The CIC 1435 provides its expertise and skills of clinical research in the infectious disease field and more specifically in Sepsis, being often the highest enroller in multicenter international Sepsis trials. For more information, please visit www.chu-limoges.fr

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, March 2015, and November 2017, respectively. The COMBACTE program management office is based in the University Medical Center Utrecht, one of the largest public health institutions in the Netherlands.

Media contact

For more information, please contact the press office of UMC Utrecht:

Phone: +31 88 755 50 00

Email: press@umcutrecht.nl



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