PRESS RELEASE

Inclusion of the first patient worldwide in the SAATELLITE-2 phase 3 trial

29 September 2022 – SAATELLITE-2, a Phase 3 to evaluate the safety and efficacy of the monoclonal antibody suvratoxumab (or 'AR-320') in the prevention of *S. aureus* infections in intubated and ventilated patients, enrolled the first patient in Limoges, France on September 6, 2022. This clinical trial is part of the COMBACTE-NET Consortium, funded through an IMI JU call for tenders, whose objective is to accelerate the development of truly novel molecules targeting bacterial infections due to multi-drug resistant (MDR) pathogens, to combat antimicrobial resistance (AMR).

COMBACTE-NET: a public-private partnership to fight antibiotic resistance

In November 2011, the European Commission, as part of its action plan to address the growing threat of antimicrobial resistance, called for "an unprecedented collaborative research and development effort to bring new antibiotics to patients" including the launch of IMI's first call for proposals in May 2012 under the European program 'New Drugs For Bad Bugs' (ND4BB).

Within the ND4BB program is the COMBACTE consortium (*Combatting Bacterial Resistance in Europe*), a unique European public/private partnership set up to promote the clinical development of new drugs in the field of anti-infectives. The diversity of experts brought together (research organizations, universities, hospitals but also pharmaceutical industries) specialized in microbiology, epidemiology or clinical trial management, offers a unique opportunity to improve and accelerate the development of anti-infectives. This consortium gathers 34 academic partners and 6 pharmaceutical companies (also called, EFPIA partners). The COMBACTE program management office is based in the University Medical Center Utrecht, one of the largest public health institutions in the Netherlands.

The development of suvratoxumab, a new monoclonal antibody

One of the objectives of the COMBACTE project is to support the clinical development of a monoclonal antibody through clinical trials sponsored by Aridis Pharmaceuticals, one of the Consortium partners.
This molecule targets a toxin produced by *Staphylococcus aureus*, which is one of the main bacteria often linked to resistance problems and associated with nosocomial infections such as ventilator-associated pneumonia (VAP), which occurs more than 48 hours after mechanical ventilation in the intensive care unit.
The Phase 2 trial, named SAATELLITE, was the first interventional trial designed and executed within COMBACTE-NET. It also represented a paradigm shift in the field of infectious diseases, investigating a pre-emptive treatment approach using a monoclonal antibody to reduce the incidence of *S. aureus* ventilator-associated and nosocomial pneumonia in *S. aureus* colonized patients receiving mechanical ventilation. A total of 213 patients were enrolled in this study at 90 sites in Europe and a reduction of 31% of pneumonia events was reported, while a 47% reduction was observed in the population aged 65 years or younger.

After the promising results of this Phase 2, a Phase 3 program was started in 2021, still within the framework of COMBACTE. This study, SAATELLITE-2, is co-led by Hasan Jafri, Chief Medical Officer at Aridis, US, and Bruno François, ICU physician at the University Hospital of Limoges, France. It aims to recruit 564 patients at 200 sites worldwide, with at least 50% in Europe.

The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking under Grant Agreement n°115523, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.

Achieving a first concrete step

After the initiation of first site in Israel in August, the first study patient was enrolled on September 6 at Limoges, France, just 6 days after this site being fully activated.

A highly productive collaboration between Aridis, the academic teams of COMBACTE and the CRO, Labcorp, applying prior lessons learned, has made it possible to go from the development of the Phase 3 study protocol, to obtaining all the necessary approvals, and to the key milestone of inclusion of this first patient, all over a span of few months.

Since the enrollment of the patient, 6 patients have been screened and 2 randomized. To date, approvals have been obtained in 6 countries across Europe, with additional approvals anticipated in additional 2 countries over the coming weeks.

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 (CIC 1435) which gathers more than 40 people (physicians, European project managers, study nurses, clinical research assistants, financial officers, medical translators, etc.). The CIC 1435 is dedicated to the promotion and implementation of clinical research within and outside the Limoges Hospital.

In addition to multicenter research projects 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. www.chu-limoges.fr

About Aridis Pharmaceuticals

Aridis Pharmaceuticals, Inc. discovers and develops novel anti-infective therapies to treat life-threatening infections, including anti-infectives to be used as add-on treatments to standard-of-care antibiotics. The Company is advancing multiple clinical stage mAbs targeting bacteria that cause life-threatening infections such as ventilator associated pneumonia (VAP) and hospital acquired pneumonia (HAP), in addition to preclinical stage antiviral mAbs. The use of mAbs as anti-infective treatments represents an innovative therapeutic approach that harnesses the human immune system to fight infections and is designed to overcome the deficiencies associated with the current standard of care which is broad spectrum antibiotics. Such deficiencies include, but are not limited to, increasing drug resistance, short duration of efficacy, disruption of the normal flora of the human microbiome and lack of differentiation among current treatments. The mAb portfolio is complemented by a non-antibiotic novel mechanism small molecule anti-infective candidate being developed to treat lung infections in cystic fibrosis patients. Aridis' clinical candidates under development include:

- AR-320 (VAP). AR-320 ('suvratoxumab') is a fully human IgG1 mAb targeting *S. aureus* alpha-toxin that is being evaluated in a Phase 3 clinical study as a preventative treatment of *S. aureus* colonized mechanically ventilated patients who do not yet have VAP.

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- AR-301 (VAP). AR-301 ('tosatoxumab') is a fully human IgG1 mAb targeting gram-positive *Staphylococcus aureus* (*S. aureus*) alpha-toxin and is being evaluated in a global Phase 3 clinical study as an adjunctive treatment of *S. aureus* ventilator associated pneumonia (VAP).
- AR-501 (cystic fibrosis). AR-501 is an inhaled formulation of gallium citrate with broad-spectrum anti-infective activity being developed to treat chronic lung infections in cystic fibrosis patients. This program is currently in Phase 2a clinical development in CF patients.

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