DaVolterra

PRESS RELEASE

Da Volterra Announces First Patient Randomized in Phase 3 Clinical Trial Evaluating the Gut Microbiome Protector DAV132 in Patients with Hematologic Malignancies

- **World's first phase 3 study of a microbiome protector, conducted as part of the European COMBACTE-NET program**
- **Consortium of European teams at the vanguard of microbiome research for patients with hematologic malignancies**
- **Objective to enroll 900 patients in approximately 80 centers worldwide**

Paris (France) and Utrecht (The Netherlands), July 26, 2021 – **Da Volterra**, a late-stage biopharmaceutical company developing novel intestinal microbiome-protective therapies, and **COMBACTE-NET**, a public-private partnership co-funded by Innovative Medicines Initiative to stoke the pharmaceutical pipeline in Europe, announced today that the first patient had been randomized in the MICROCARE Phase 3 clinical trial. This follows the authorizations obtained from 7 regulatory authorities in Europe, including France, Germany, Spain and Denmark.

The MICROCARE trial is evaluating DAV132, a first-in-class and strongly innovative microbiome protector, and shall enroll 900 patients newly-diagnosed with acute myeloid leukemia or high-risk myelodysplastic syndrome treated with intensive chemotherapy in approximately 80 centers worldwide.

"We believe that protecting the microbiome of patients with acute myeloid leukemia is a clinically meaningful goal, as patients with disrupted microbiome have more life-threatening complications and a lower survival rate", said **Fabien Vitry, M.D., Chief Medical Officer of Da Volterra**. *"This study is a stepping stone for microbiome-oriented therapies and could pave the way to new treatment options for all patients with cancer."*

MICROCARE is a randomized, placebo-controlled, parallel-group trial. Its overarching objective is to demonstrate that DAV132 contributes to decreasing the occurrence of life-threatening complications and to reducing the mortality of patients with hematologic malignancies undergoing several cycles of chemotherapy.

"With all my team, we are glad to have recruited the first patient in MICROCARE.", said **Dr. Christine Robin, principal investigator at the Henri-Mondor Hospital (Creteil, France).**

The primary endpoint will be the occurrence of *Clostridioides difficile* infection, a severe and life-threatening complication which is triggered by the disruption of the intestinal microbiome. The study will also assess the efficacy of DAV132 in protecting intestinal microbiome diversity, preventing intestinal colonization with potentially pathogenic bacteria, preventing bloodstream infections and improving Overall Survival.

"The MICROCARE trial offers an opportunity for change for patients and physicians alike, and it is also the proof that the clinical network of COMBACTE-NET, bolstered by IMI support, is up to the challenge of performing high-stake clinical studies." commented **Prof. Marc Bonten, M.D., Ph.D., Academic**

Coordinator of COMBACTE-NET. *"All the partners of COMBACTE-NET are committed to making MICROCARE a real success for all stakeholders."*

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About Da Volterra

Headquartered in Paris (France), Da Volterra is a late-stage biopharmaceutical company developing innovative products to prevent intestinal microbiome dysbiosis in patients with cancer.

The company's lead product-candidate, DAV132, is the world's most advanced product protecting against the clinical consequences of microbiome dysbiosis. It is in Phase 3 clinical trial and should be available for physicians and patients within a few years.

DAV132 is a unique and first-in-class product designed to inactivate antibiotics as they reach the colon and prevent them from disrupting the intestinal microbiome. It has been proved effective in volunteers and patients. It is safe and does not impact the efficacy of antibiotics in treating or preventing infections.

DAV132 is of particular interest to patients at risk of developing life-threatening complications caused by the use of antibiotics. DAV132 will be administered concomitantly with antibiotics in order to:

- Decrease the occurrence of life-threatening complications such as severe infections and graft-versus-host disease in patients with hematologic malignancies.
- Preserve the efficacy of immune checkpoint inhibitors and increase the survival of patients with solid tumors taking antibiotics.

To date, 496 human subjects have received DAV132 in six Phase 1 and one Phase 2 clinical studies with no safety risk observed. The recent success of the Phase 2 SHIELD study has shown that DAV132 is safe for use in hospitalized elderly patients with several comorbidities and taking concomitant medications. It has also demonstrated that DAV132 is able to protect the intestinal microbiome from antibiotic damage. Preventing microbiome disruption and its harmful consequences is an important, and largely unmet, medical need.

For more information on Da Volterra and DAV132, visit https://davolterra.com

About the IMI ND4BB Program & COMBACTE-NET

The Innovative Medicines Initiative's (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 is 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 products in the anti-infectives field.

For more information on IMI, visit http://www.imi.europa.eu

Within the ND4BB program, the COMBACTE-NET consortium represents the first European public-private partnership established to promote the clinical development of new medicines in the fight against antimicrobial resistance. The diverse group of experts comprising the consortium membership specialize 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.

For more information on the COMBACTE projects, visit http://www.combacte.com

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