



## Da Volterra Receives first Authorizations from Regulatory Authorities in EU Countries to Initiate its Phase 3 Clinical Trial Evaluating the Microbiome Protector DAV132 in Patients with Hematologic Malignancies

- **World-first phase 3 study of a microbiome protector**
- **Da Volterra becomes a pioneering late-stage clinical company and accelerates its growth to maintain leadership in the microbiome field**

**Paris (France), February 3<sup>rd</sup>, 2021** – **Da Volterra**, a clinical-stage biopharmaceutical company developing innovative products to prevent the life-threatening effects antibiotics have on the gut microbiome of cancer patients, announced today that it received approval to start enrolling patients in a Phase 3 clinical trial evaluating DAV132, its first-in-class microbiota protector. Authorizations by two regulatory authorities in Europe, the French National Agency for Medicines and Health Products Safety (ANSM) and the Hungarian National Institute of Pharmacy and Nutrition (OGYÉI), represent an important milestone for Da Volterra. The trial, named MICROCARE, is conducted in collaboration with partners of the COMBACTE-NET consortium and is co-funded by the Innovative Medicines Initiative (IMI).

The MICROCARE study will enroll 900 patients from clinical sites mainly in Europe and in the USA. The European Coordinator is Professor Maria J.G.T. Vehreschild, MD, Head of Infectious Diseases at Frankfurt University Hospital. The overarching objective of the trial is to demonstrate that DAV132 contributes to decrease the occurrence of life-threatening complications and to reduce the mortality of patients with hematologic malignancies undergoing several cycles of chemotherapies. The primary endpoint will be the occurrence of *Clostridioides difficile* infection, a severe and life-threatening comorbidity. 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 use of DAV132 in patients with Acute Myeloid Leukemia and Myelodysplastic Syndrome patients treated with intensive chemotherapy is supported by a strong scientific and medical rationale and offers a novel and differentiated strategy with the potential to bring patients multiple benefits linked to microbiome protection, including better survival.”* declared Prof. Maria J.G.T. Vehreschild.

To date, 496 human subjects have been exposed to 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 showed that DAV132 was safe for use in hospitalized elderly patients with several comorbidities and taking concomitant medications. It also demonstrated that DAV132 was able to protect the intestinal microbiome from antibiotic damage. *“It is an historic moment for DAV132 and the beginning of a new era for hemato-oncology patients: now, for the first time, we will be able to protect the microbiome of these patients in spite of their massive antibiotic use. At Da Volterra, all the team is very proud of being again in the vanguard of research for the benefit of patients.”* commented Dr. Fabien Vitry, Chief Medical Officer of Da Volterra.

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### **About the MICROCARE Study:**

MICROCARE is a multicenter, randomized, placebo-controlled, parallel-arm clinical trial to evaluate the efficacy of DAV132 in patients with newly-diagnosed Acute Myeloid Leukemia or high-risk Myelodysplastic Syndrome treated with intensive chemotherapy.

### **About DAV132:**

DAV132 is a unique and first-in-class product designed to inactivate antibiotics circulating in the colon and disrupting the gut microbiome. DAV132 has already demonstrated its ability to safely and effectively preserve the intestinal microbiome of healthy volunteers and patients in multiple clinical trials, without impacting the clinical efficacy of antibiotic treatments.

DAV132 is primarily developed in cancer patients for whom antibiotic use is both life-saving and life-threatening:

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

DAV132 is the world most advanced product protecting against the clinical consequences of intestinal microbiome dysbiosis and shall be available for physicians and patients within a few years.

### **About Da Volterra:**

Headquartered in Paris (France), Da Volterra is a clinical-stage biopharmaceutical company developing innovative products to prevent the life-threatening gut dysbiosis in patients with cancer.

For more information on Da Volterra, visit <https://davolterra.com/>

### **About the IMI ND4BB Program & COMBACTE-NET:**

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 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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