DaVolterra

PRESS RELEASE

Da Volterra Receives FDA Fast Track Designation for its Novel Microbiome Protector DAV132

- **FDA Fast Track Designation has been granted to DAV132 for the prevention of *Clostridioides difficile* infection, a life-threatening condition with persistent unmet medical need, especially in cancer patients**
- **DAV132 is a first-in-class microbiome protector with positive Phase 2 data and a Phase 3 being launched in patients with hematologic malignancies**

Paris (France), April 6th, 2021 **– Da Volterra**, a late-stage biopharmaceutical company developing new intestinal microbiome-protective therapies, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for its first-in-class microbiome protector, DAV132, in the prevention of *Clostridioides difficile* infection (CDI) in patients at high risk of CDI. Da Volterra is about to launch a Phase 3 clinical trial (called MICROCARE) evaluating DAV132 in patients with hematologic malignancies.

The FDA Fast Track Designation intends to facilitate the development and review of drug candidates for treating or preventing serious conditions that demonstrate the potential to address unmet medical needs. The Fast Track Designation confers several advantages including more frequent interactions with the FDA to discuss development plans and access to Accelerated Approval and Priority Review. This expedited program will allow Da Volterra to make rapid progress in bringing DAV132 to market and to patients sooner.

"By awarding Fast Track Designation for DAV132, the FDA has recognized its high value for patients in protecting the gut microbiome, notably to prevent C. difficile infection, which can be life-threatening, particularly in cancer patients. It is a major acknowledgement as we are about to launch a Phase 3 clinical study for cancer patients who currently have no good preventive option", said Florence Séjourné, Da Volterra's Chief Executive Officer.

"*We are pleased to have received Fast Track designation from the FDA and look forward to working closely with them to expedite the clinical development of DAV132",* said Fabien Vitry, Da Volterra's Chief Medical Officer.

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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 most advanced product protecting against the clinical consequences of microbiome dysbiosis. It is entering a Phase 3 clinical trial and shall 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 to treat infections.

DAV132 is of particular interest to patients for whom antibiotic use is life-saving but may also cause life-threatening complications. DAV132 will be administered concomitantly with antibiotics in order to:

- Decrease the occurrence of life-threatening complications such as *C. difficile* infection or 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 study (SHIELD) 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.

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

About Microbiome Protection

The intestinal microbiome is increasingly seen as essential to human health and a poor diversity of the microbiome is thought to trigger several pathologies and clinical complications. *C. difficile* infection is one of these complications: it endangers patients and strongly reduces their quality of life. Since 2013, *C. difficile* has been considered as an urgent Public Health threat by the US Centers of Disease Control. To date, there is no drug available to protect the microbiome and prevent *C. difficile* infection occurrence in patients receiving antibiotics. Preventing microbiome disruption and its harmful consequences is an important, and largely unmet, medical need.

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