



Da Volterra Announces Enrollment of First Patients in SHIELD, a Phase 2 Clinical Trial with DAV132, a Novel Microbiota Protective Therapy

- SHIELD trial evaluates the safety and efficacy of DAV132 to protect the intestinal microbiota in hospitalized patients at high-risk of *Clostridium difficile* infection when receiving antibiotic treatments.
- The clinical study is a multi-center, randomized, parallel-group comparative trial initiated in 29 clinical sites in several countries in Europe.

Paris (France), 20 December, 2018 – Da Volterra, a clinical-stage microbiome company focused on developing new therapeutics to protect the intestinal microbiota, announced today that it has enrolled the first patients in a Phase 2 trial called SHIELD, evaluating its innovative product DAV132 in patients at high-risk of *Clostridium difficile* Infection (CDI). DAV132 is Da Volterra’s most advanced product designed to preserve the intestinal microbiota and to prevent life-threatening conditions such as CDI due to antibiotic treatments.

SHIELD is a multi-center, randomized, parallel-group comparative trial planned to be initiated in 29 clinical centers in 4 countries in Europe (Germany, Romania, Bulgaria and Serbia). The trial is recruiting 260 hospitalized patients at high-risk of CDI, receiving oral or intravenous fluoroquinolone antibiotics (moxifloxacin, levofloxacin, ciprofloxacin) for the treatment of acute infections (lower respiratory tract infections or complicated urinary tract infections) or for prophylaxis of febrile neutropenia.

Patients selected for the SHIELD trial combine several known risk factors for CDI: either they had a previous CDI in the past 6 months, or they are older than 65 with at least two of the following risk factors: previous exposure to antibiotics, long-term hospitalization/nursing care in the past 3 months, severe comorbidities including malignant diseases.

Patients are randomized in 2 groups: they will either receive the antibiotic treatment alone (standard of care) or DAV132 with the antibiotic treatment.

The primary objective of the SHIELD phase 2 study is to assess the safety of DAV132 associated with antibiotics in the selected patient population. The clinical efficacy on the reduction of CDI and antibiotic-associated diarrhea between the 2 groups will be evaluated, together with DAV132 protection of the intestinal microbiota measured by reduction of fecal antibiotics concentration, maintenance of bacterial diversity and reduction of the emergence of antibacterial resistance.

Annie Ducher, Chief Medical Officer of DA VOLTERRA, commented: *“Based on the very encouraging data generated with DAV132 in healthy subjects published in the Journal of Infectious Diseases earlier this year (<https://doi.org/10.1093/infdis/jix604>), we expect to demonstrate the safe use of DAV132 and to get convincing data in a specific patient population which would highly benefit from a reduction of antibiotics deleterious effects on the intestinal microbiota.”*

DAV132 is being developed as a medical device in Europe and drug in the USA. Although conducted in Europe, the clinical trial protocol was presented and positively received by the Food & Drug Administration in the USA, where preventing *Clostridium difficile* infection is a high priority for the Centers for Disease Control and Prevention.

About DAV132:

DAV132 is a novel, patent-protected, oral treatment developed to protect the intestinal microbiota from damaging side effects of antibiotics or other small molecules. With a novel and unique mechanism of action, DAV132 is primarily developed for the prevention of *Clostridium difficile* infection, which is mainly induced by antibiotics. Co-administered with antibiotics, DAV132 has demonstrated its ability to selectively and safely suppress antibiotic disruption of the intestinal microbiota in multiple clinical trials in healthy volunteers.

About *Clostridium difficile* infection:

Clostridium difficile ("C. diff") is a gram-positive, spore-forming bacterium living in the colon where it is normally in equilibrium with the other bacteria that live there. Antibiotics used to treat infections elsewhere in the body can disrupt the normal bacterial equilibrium of the colon and allow *C. diff* to overgrow and begin producing toxins. This results in *Clostridium difficile* infection which comes in a variety of clinical presentations ranging from mild diarrhea to severe infection with fulminant colitis and can lead to septic shock and death. *C. diff* is well recognized as the leading cause of antibiotic-associated diarrhea, having a significant impact in both healthcare and community settings.

About Da Volterra:

Headquartered in Paris (France), Da Volterra is a clinical-stage biopharmaceutical company whose vision is to be a trusted and acknowledged leader in the microbiota field. Da Volterra develops novel strategies aimed at protecting the intestinal microbiota and preventing multi-resistant and life-threatening infections for which the medical need is increasing. <https://davolterra.com>

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