DaVolterra

PRESS RELEASE

Da Volterra Announces Completion of Patient Recruitment for its Phase 2 Clinical Study with DAV132, a Novel Microbiota Protective Therapy

- **260 patients enrolled in the SHIELD Phase 2 study, first headline results expected by the end of the year**
- **2 additional Phase 1 studies have been launched in the USA and in France**
- **First IND for DAV132 cleared by the FDA**

Paris (France), 3rd of July, 2019 **– Da Volterra**, a clinical-stage biopharmaceutical company developing new therapeutics to protect the intestinal microbiota, announced the completion of patient recruitment for its Phase 2 trial 'SHIELD' evaluating DAV132 in patients receiving antibiotics.

DAV132 is Da Volterra's most advanced product, designed to preserve the intestinal microbiota of patients from antibiotic-induced disruption. It targets several clinical benefits such as prevention of *Clostridioides difficile* infection and increased clinical response to Immune Checkpoint Inhibitors (ICI) in patients receiving antibiotics and treated with ICI.

SHIELD is a multi-center, randomized, parallel-group comparative trial in which 260 patients were recruited in 29 clinical centers in 4 countries in Europe (Germany, Romania, Bulgaria, and Serbia). The patients enrolled received oral or intravenous fluoroquinolone antibiotics for the treatment of lower respiratory tract infections, complicated urinary tract infections or for prophylaxis of febrile neutropenia. They were randomized in two groups and received the antibiotic treatment either alone (standard of care) or with DAV132.

The study was designed to investigate the safety and efficacy of DAV132 associated with antibiotics to preserve the intestinal microbiota in the target patient population.

"We are pleased to announce the completion of recruitment for our first-in-patient Phase 2 study for our innovative and most advanced product, DAV132. We would like to thank all patients and investigators who contributed to the achievement of this significant step in our development. We are looking forward to the results from the study by the end of the year" said Florence Séjourné, CEO of Da Volterra. *"We are also very pleased to announce that the USA FDA (Food and Drug Administration) has approved the first IND for DAV132. Now, two new Phase 1 clinical trials have been launched in the US and in France, to reinforce our understanding of DAV132 profile in humans, especially with beta-lactam antibiotics."*

Top-line results of the Phase 2 and of the Phase 1 trials are expected by the end of the year and beginning of 2020.

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About DAV132:
DAV132 is a novel, patent-protected, oral treatment developed to protect the intestinal microbiota from the damaging side effects of antibiotics and other small molecules. 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 patients taking antibiotics, DAV132 is developed for the prevention of *Clostridioides difficile* infection and as an add-on therapy to potentiate the efficacy of immune checkpoint inhibitors.

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 to address large unmet medical needs in the oncology, haemato-oncology, and infectious diseases' spaces. https://davolterra.com

Contact:
Da Volterra - Florence Séjourné, CEO - Tel: +33 1 58 39 32 20 - press@davolterra.com