



## **Da Volterra presents new data supporting DAV132 as a promising candidate to protect the intestinal flora and prevent severe *Clostridium difficile* infections**

- ***The CL1001 clinical trial demonstrates the adequate targeted delivery of DAV132 to the ileum and the colon and its adsorbing effects.***
- ***The preclinical study performed in a reference animal model of *Clostridium difficile* infection confirms the protective effects of DAV132.***
- ***The Company will present these data in two posters at the ECCMID conference taking place in Barcelona on May 10-13, 2014.***

**Paris (France), May 9th, 2014** – Da Volterra, a leading biopharmaceutical company in the field of bacterial resistance, announces today very promising new results about DAV132 in the prevention of the side effects of antibiotics and the occurrence of severe *Clostridium difficile* infections. The Company presents two posters at ECCMID 2014 (the European Conference of Microbiology and Infectious Diseases) taking place in Barcelona on May 10-13, 2014.

With a novel and unique mechanism of action, DAV132 is a product candidate aiming at protecting the intestinal flora from the side effects of administered antibiotics, hence preventing *Clostridium difficile* infections. This pathogenic bacterium causes serious and potentially lethal gastro-intestinal infections. To this end, DAV132 captures the antibiotic residues in the digestive tract which are at the origin of the alterations of the intestinal flora, while maintaining the efficacy of the antibiotic treatment. As a consequence the flora disruption adverse effect is avoided.

- The CL1001 study, a phase I clinical trial performed in the spring 2013 at the Medicine University of Greifswald (Germany) with 18 healthy volunteers, showed the expected targeted delivery of DAV132. The results demonstrate that DAV132 effectively exerts its adsorbing effect in the ileum and the colon, whereas DAV132 does not interfere upstream with antibiotics in the small intestine. Antibiotic treatments given together with DAV132 would thus be optimized, DAV132 reducing the alterations of the flora and their consequences such as *Clostridium difficile* infections or the emergence of resistant bacteria.
- A preclinical study performed in the reference hamster model of *Clostridium difficile* infections evidenced the preventive effect of DAV132. Animals treated with moxifloxacin only (an antibiotic) showed 100% mortality (no survivor after 7 days) in the experiment. Interestingly, animals treated with moxifloxacin and DAV132 during 5 days are protected from the lethal impacts of *Clostridium difficile*. The protective effect of DAV132 is dose-dependent and a total protection is reached at the highest doses. This study in a predictive model of the disease illustrates the protective effects of DAV132, co-administered with an antibiotic treatment, against *Clostridium difficile* infections.

The detailed results are presented in two posters\* at the ECCMID conference (European Congress of Clinical Microbiology and Infectious Diseases) taking place in Barcelona on the 10-13 May, 2014.

\* **DAV132, developed to prevent side effects of antibiotics in the gut flora: Results of a pilot cross-over study in healthy volunteers.** A. Ducher, C. Modess, W. Weitschies, W. Siegmund, J. Dressman, V. Augustin, C. Feger, A. Andremont and J. de Gunzburg.

**DAV131, an oral adsorbent-based product, exerts a dose-dependent protection of hamsters against moxifloxacin-induced *Clostridium difficile* lethal infection.** C. Miossec, S. Sayah-Jeanne, V. Augustin, E. Chachaty, W. Weiss, T. Murphy, M. Pulse, A. Andremont, and Jean de Gunzburg

**Florence Séjourné, CEO of Da Volterra, declared:** «We are particularly proud to present these results to the scientific community, illustrating the very innovative and unique profile of DAV132. The control of *Clostridium difficile* infections and antibiotic resistance are major public health challenges. We look forward to advancing the development of DAV132, and are convinced that Da Volterra is well positioned to push forward its innovative product pipeline to meet these urgent medical needs ».

#### **About *Clostridium difficile* infections:**

In the last decade, the epidemics of *Clostridium difficile* became even harder to control. Spreading in the environment from infected people whose intestinal flora was disrupted by antibiotic treatments, *Clostridium difficile* infections raise growing concerns and cause an increasing number of infections. According to a study published in Oct 2013 by the U.S Centers for Disease Control and Prevention, *Clostridium difficile* infections cause 250.000 infections and 14.000 deaths per year in the United States for a medical cost superior to 1 billion dollars. In Europe, the cost of this pathology is estimated to reach more than 3 billion euros a year.

#### **About Da Volterra:**

Da Volterra is a biopharmaceutical company based in Paris (France) and develops new strategies for the prevention and the treatment of multi-resistant and life-threatening infections for which the medical need is increasing. While antibiotics resistance threatens current medical practice, Da Volterra's innovative approaches promise a substantial medical progress, fitting the expectations of healthcare professionals. Its most advanced product, DAV132, is developed to prevent *Clostridium difficile* infections, and is planned to enter phase II clinical trial by 2015.

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