



## Da Volterra Announces Positive Preclinical Results in Immuno-Oncology with DAV132, a Revolutionary Gut Protector

- **DAV132 was demonstrated to prevent antibiotic-induced loss of responsiveness to PD-1 blockade cancer therapy in a well-established animal model**
- **A Phase 2 clinical trial evaluating DAV132's potential in immuno-oncology will start by the end of the year**

**Paris (France), April 28, 2022** – Da Volterra, a clinical-stage biopharmaceutical company pioneering the new therapeutic class of gut protective therapies, announced today convincing preclinical results in the field of immuno-oncology.

In a study conducted in collaboration with Pr. Bertrand Routy's lab at the University of Montreal Hospital Research Centre (CRCHUM), Da Volterra's scientists investigated whether DAV132, a clinical-stage gut microbiome protector, could prevent antibiotic-induced loss of responsiveness to PD-1 blockade cancer therapy using a well-established fecal microbiota transplantation (FMT) approach in mice. This follows the publication of more than 50 articles and 12 meta-analyses demonstrating that antibiotics negatively impact the response to PD-1 blockade cancer therapy and impair survival of patients affected by cancers such as metastatic non-small-cell lung carcinoma, metastatic melanoma and renal cell carcinoma.

In summary, CRCHUM and Da Volterra's scientists demonstrated that:

- The gut microbiome of healthy human volunteers treated with an antibiotic (ceftazidime-avibactam) no longer enables the anti-tumor response to anti-PD-1 antibodies when transferred to tumor-bearing germ-free mice (that were otherwise responding before antibiotic treatment).
- The gut microbiome of healthy human volunteers treated with DAV132 in addition to the antibiotic (ceftazidime-avibactam) maintains the anti-tumor response to anti-PD-1 antibodies when transferred to tumor-bearing germ-free mice.

This confirms that the response to anti-PD-1 antibodies is at least partly mediated by the intestinal microbiome and that microbiome disruption induced by antibiotics can reduce the response to antibodies – a deleterious consequence which can be avoided with DAV132.

These promising data will be submitted shortly for presentation at a medical congress and for publication in a peer-reviewed scientific journal. *"This is a clear breakthrough in the field and encourages us to move forward quickly with our next clinical trial to evaluate the efficacy of DAV132 in improving the survival of lung cancer patients treated with a PD-1 blockade cancer therapy that have received antibiotics. We are eager to present these compelling results to the scientific and medical community to raise awareness around the importance of the intestinal microbiome in oncology."* said Dr. Jean de Gunzburg, PhD, Chief Scientific Officer at Da Volterra.

If confirmed in further studies, the results suggest that DAV132 may be instrumental in increasing the life expectancy of cancer patients treated with immunotherapies. According to real world data collected by Da Volterra, close to 40% of patients with lung cancer are prescribed antibiotics around the start of their immunotherapy and could thus benefit from the treatment.

Following this successful collaboration, Pr. Bertrand Routy and his team are currently conducting additional preclinical studies with DAV132 in immuno-oncology. Da Volterra plans to launch a Phase 2 clinical trial in immuno-oncology by the end of the year.

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### **About Da Volterra**

Headquartered in Paris (France), Da Volterra is a clinical-stage biopharmaceutical company pioneering a new therapeutic class: gut microbiome protective therapies in oncology.

The company's lead asset, DAV132, is the world's most advanced product protecting against the clinical consequences of microbiome disruption in cancer patients. DAV132 is a first-in-class oral product, co-administered with antibiotics and chemotherapy to maintain patients' gut microbiome health during these critical treatments. DAV132's development is supported by robust data from 7 clinical trials with a demonstrated mode of action, biological efficacy and safety in 500 patients and human volunteers.

Protecting patients from microbiome disruption is an important and largely unmet medical need, in particular in patients with cancer. DAV132 is developed to increase patients' response to cancer immunotherapies (anti-PD-(L)1 and CAR-T), and reduce the occurrence of severe, life-threatening complications, with the overall objective of improving the survival and quality of life of cancer patients.

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

### **Contact**

Florence Séjourné, Chief Executive Officer of Da Volterra  
+33 1 58 39 32 20 – [press@davolterra.com](mailto:press@davolterra.com)