



Da Volterra Announces Positive Results of a Phase 1 Drug-Drug Interaction Study Demonstrating No Interaction Between DAV132 and Two Narrow Therapeutic Index Drugs

Paris (France), 3rd of December, 2019 – **Da Volterra**, a clinical-stage biopharmaceutical company developing innovative products to protect the intestinal microbiota, announced the results of DAV132-CL-1005, a Phase 1 clinical study which investigated the potential effect of DAV132 on the bioavailability of warfarin or clonazepam, two widely used drugs with narrow therapeutic index (drugs for which suboptimal plasma levels may lead to potential serious clinical outcomes).

DAV132 is Da Volterra’s most advanced product, designed to preserve the intestinal microbiota of patients from antibiotic-induced disruption. It is a novel colon-targeted adsorbent that aims at several clinical benefits such as prevention of *Clostridioides difficile* infections, prevention of colonization by multi-drug resistant organisms and their dissemination, as well as preservation of the clinical response to Immune Checkpoint Inhibitors in cancer patients receiving antibiotics. Results from previous studies¹ already showed that the adsorbent within DAV132 did not impact the plasma levels of co-administered antibiotics.

DAV132-CL-1005, a single center, randomized, cross-over, open-label study, was performed in the USA after FDA approved DAV132 IND in January 2019. Thirty-nine healthy volunteers received warfarin (5 mg), an oral anticoagulant, or clonazepam (1 mg), an oral anti-convulsant, and DAV132 (7.5 g three times a day). **DAV132 impacted neither the plasma pharmacokinetics and pharmacodynamics of warfarin nor the plasma pharmacokinetics of clonazepam**, meaning that no specific recommendation will be required when DAV132 will be given in co-administration with those drugs. There were no safety concerns associated with DAV132 intake and it was well tolerated in all volunteers, confirming the excellent safety profile demonstrated in previous studies.

“We are very pleased with the results of this Phase 1 study: we have demonstrated once again that the adsorbent within DAV132 was not delivered before the late ileum. This is of tremendous importance as it means that DAV132 can be safely administered with narrow therapeutic index drugs, without any risk of interference with their absorption in the small intestine. Together with the [SHIELD](#) Phase 2 trial whose results are expected for the beginning of next year, we are actively generating solid clinical data to support the use of DAV132 in patients.” declared Annie Ducher, CMO at Da Volterra.

About DAV132:

DAV132 is a novel, patented colon-targeted adsorbent developed to protect the intestinal microbiota from the damaging effects of 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 patients taking antibiotics, DAV132 is developed for the prevention of *Clostridioides difficile* infections, prevention of colonization by multi-drug resistant organisms and their dissemination, as well as add-on therapy in cancer patients treated by Immune Checkpoint Inhibitors.

¹ <https://doi.org/10.1093/infdis/jix604> and <https://doi.org/10.1002/jcph.359>

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 infectious disease, gastroenterology, oncology, and hemato-oncology spaces. <https://davorterra.com>

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