



Versantis Announces FDA Grants Orphan Drug Designation to VS-01 for the Treatment of Acute-on-Chronic Liver Failure

A NEW LANDMARK CONSOLIDATING A SIMILAR DESIGNATION PREVIOUSLY GRANTED BY THE EMA TO VS-01 FOR THE TREATMENT OF ACUTE LIVER FAILURE.

Zurich, Switzerland, July 17th, 2017 – Versantis, a pharmaceutical company reinventing the diagnosis, prevention, and treatment of patients with liver diseases, today announces that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to VS-01 for the treatment of patients with acute-on-chronic liver failure (ACLF). VS-01 is a proprietary liposomal fluid infused in the abdominal cavity where it enhances the elimination of ammonia and other toxic metabolites responsible of the poor prognosis in ACLF patients.

“ACLF is a recently recognized condition affecting patients with cirrhosis and rapidly progressing to encephalopathy, multi-organ failures, and fatalities. VS-01 is the first drug therapy to simultaneously support both liver and kidneys and promises to transform the lives of affected individuals and their families.” said Dr. Vincent Forster, CEO and co-founder of Versantis. “The granting of orphan drug designation in the U.S. is an important step forward in the development of VS-01 and highlights the high unmet medical need for new therapies in this indication. We are on track to file a clinical trial application in late 2018 and committed to bringing VS-01 to patients in a timely manner.” added Meriam Kabbaj, COO and co-founder of Versantis.

About orphan drug designation

This designation is granted by the FDA to drugs and biologics affecting fewer than 200'000 people in the U.S. It provides incentives to assist and encourage the development of such products, which may include assistance in clinical study design, tax credits related to clinical trial expenses, exemptions from certain FDA application fees, and potential market exclusivity for seven years following approval.

About ACLF

Acute-on-chronic liver failure is a rare disease characterized by an acute decompensation of the liver in a patient with preexisting damages caused by cirrhosis. This condition is often supplemented by hepatic encephalopathy, a debilitating neurologic alteration rapidly progressing into coma and death. ACLF affects about 200'000 patients yearly in the U.S. and the E.U. and continues to spread due to the aging population, and a higher prevalence of diabetes, obesity, alcohol, and drug consumption.

About Versantis

Versantis is a Swiss pharmaceutical company, Spin-off of ETH Zurich, developing breakthrough liver disease medicines and diagnostics addressing high unmet medical needs. Versantis recently closed a Series A with Redalpine Venture Partners, Altus Partners, Healthequity, and Occident Group to advance its lead candidate, VS-01, to first-in-human. VS-01 is currently at preclinical stage and has the potential to be the first drug for acute liver diseases simultaneously supporting multiple failing organs. VS-01 targets 3 rare indications and so far received an orphan designation for two of them, ACLF and acute liver failure in the U.S. and the E.U., respectively. Besides acute indications, Versantis tackles the prevention and the diagnosis of hepatic encephalopathy in chronic liver disease patients with VS-02, an oral polymer-based product, and TS-01, an innovative clinical test for ammonia measurements. Both represent large market opportunities and significant upsides for Versantis.

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