Versantis to Present Positive Phase 1b Data at AASLD for VS-01 in Patients with Decompensated Cirrhosis

VS-01 to Advance into Phase 2a study in Patients with Acute on Chronic Liver Failure

Zurich, Switzerland, November 15, 2021 – Versantis, a clinical-stage biotechnology company developing novel therapies for orphan liver and pediatric diseases, today announced that positive Phase 1b clinical data from a study of its lead investigational, orphan-designated product, VS-01, in 12 hospitalized patients with decompensated liver cirrhosis will be presented at the American Association for the Study of Liver Diseases (AASLD) annual meeting. The data show that VS-01 was safe and well tolerated in these patients, and demonstrated promising early indications of efficacy in this clinical study. VS-01 is a potentially lifesaving, multi-organ support therapy that aims to timely reverse Acute-on-Chronic Liver Failure (ACLF) by enhancing the clearance of ammonia and other toxins following paracentesis.

The Abstract selected for oral presentation is as follows:

Oral Presentation Title: Safety and Preliminary Efficacy and Pharmacokinetics of Intraperitoneal VS-01 Infustions in Patients with Decompensated Liver Cirrhosis: A First-in-Human, Open-label, Phase 1b Clinical Trial
Presenter: Dr. Frank Erhard Uschner, Section for Translational Hepatology, Department of Internal Medicine I, Goethe University Clinic Frankfurt,
Session Date/Time: Monday, November 15, 2021, 12:30 p.m. EST

The annual Liver Meeting, held by AASLD, brings together attendees from around the world to exchange the latest research, discuss new developments in treatments, and network with others in the field.

The primary objective of this single-center first-in-human study was to evaluate the safety and tolerability of *i.p.*-administered VS-01 on top of standard of care in cirrhotic patients with ascites and mild hepatic encephalopathy following single and multiple intraperitoneal administrations. The secondary objectives were to gather preliminary PK, PD, and clinical efficacy data. In total, all 12 patients completed treatment in the Department of Internal Medicine I, Goethe University Frankfurt

and were assigned to receive either a single dose of VS-01 (Part A; n=9) or four consecutive doses (Part B; n=3). Following the drainage of ascites in these patients, VS-01 was then infused into the peritoneal cavity via the existing paracentesis catheter and removed after a dwell time of 2-3 hours. No treatment-related serious adverse events were reported and no patient discontinued treatment due to an adverse event. VS-01 also demonstrated promising clinical efficacy results, including a high and dose-dependent ammonia clearance, promising improvement in hepatic encephalopathy based on psychometric tests, and increased peritoneal clearance of ACLF-related metabolites.

"The data show that VS-01 is safe and well tolerated in cirrhotic patients with ascites and covert (mild) hepatic encephalopathy, so very promising. We were able to administer VS-01 using standard hospital equipment via the therapeutic paracentesis catheter, which we believe can easily be incorporated into standard of care for patients," said Prof. Dr. Trebicka, the principal investigator and head of the Section of Translational Hepatology in Goethe University Frankfurt. "There are very few treatments available for these patients and VS-01 is complementary to those, so we are excited to continue advancing it's development and hopefully generate the data supporting this ground-breaking clinical approach."

"VS-01 represents a promising new therapeutic for the potential treatment of patients with ascites and acute complications of cirrhosis. The data from this early study were very promising and importantly show that VS-01 appears to be safe and well tolerated in these patients. The amomonia and ACLF metabolites clearance data is particularly encouraging," added Vincent Forster, CEO and co-Founder of Versantis. "The successful completion of this study supports future development of VS-01. We are now preparing to initiate a multi-center Phase 2a study in patients with ACLF, a seriously underserved and under-resourced indication. Together with our pipeline of innovative products, we are committed to developing and commercializing new treatment options for patients suffering from acute liver diseases."

About Acute-on-Chronic Liver Failure (ACLF)

ACLF is an underserved medical condition, which, despite best possible available care, is associated with high short-term mortality. It is characterized by an abrupt life-threatening worsening of a pre-existing chronic liver disease (e.g., cirrhosis) resulting in liver and extrahepatic organ failure rapidly progressing into coma and death. Every year at least 150'000 patients are hospitalized with ACLF in the US and EU. The incidence is growing due to a higher prevalence of diabetes, obesity, fatty liver diseases, and alcohol consumption. By timely reversing ACLF and the multi-organ complications arising from cirrhosis, VS-01 aims to improve outcomes in these patients and relieve the growing health and economic burden of this advanced liver disease.

About Versantis

Versantis is a clinical stage biotechnology company focused on addressing the growing, un-met medical need in liver diseases. With a pipeline of drug and diagnostic products covering chronic and acute indications, Versantis believes it can revolutionize current standard of care for patients

suffering from acquired and genetic hepatic deficiencies. Versantis' lead program, VS-01, is in clinical development as a first-line therapy for the timely reversal of acute-on-chronic liver failure (ACLF). It harnesses Versantis' proprietary scavenging liposomes to extract toxins from the body and, if approved, will be the first drug to take advantage of the intraperitoneal route to potentially support the liver, kidneys and brain, the organs that most often fail in cirrhotic patients. VS-01 has received orphan drug designation (ODD) from the EMA and U.S. FDA, as well as a Rare Pediatric Diseases Designation from the U.S. FDA for Urea Cycle Disorders. Founded by scientists from ETH Zurich with entrepreneurial drive, Versantis has built a team and Board of seasoned industry executives with a proven ability to advance novel therapies from the idea stage into clinical development. The company is headquartered in Zurich, Switzerland. For additional information, visit: www.versantis.ch.

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