Versantis Announces Positive Phase 1b Results for VS-01 in Patients with Decompensated Cirrhosis

Promising data supports advancing VS-01 into Phase 2a POC study in Acute on Chronic Liver Failure

Zurich, Switzerland, March 17th, 2021 – Versantis, a clinical-stage company developing novel therapies for orphan liver and pediatric diseases, today announced positive results from a Phase 1b clinical trial of VS-01 in decompensated liver cirrhosis. VS-01 was found to be safe and well tolerated in this first-in-human, single ascending and multiple dose study led by Prof. Dr. Jonel Trebicka at the Goethe University Hospital Frankfurt. VS-01 is a potentially lifesaving, multi-organ support therapy that aims to reverse Acute-on-Chronic Liver Failure (ACLF) by enhancing the clearance of ammonia and other toxins from the body.

"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. "There are very few treatments available for these patients and VS-01 is complementary to those, so we are excited to continue the trial and hopefully generate the data supporting this ground-breaking clinical approach."

The primary objective of the 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, 12 patients were successfully treated, 9 in the single ascending dose part (3 doses) and 3 in the multiple dose (daily treatment for 4 days) part of the study.

The results showed that VS-01 was safe and well tolerated, with no dose-limiting toxicities or unexpected safety signals. No serious adverse events (AE) were reported, and no patients discontinued because of an AE. Patients receiving multiple doses of VS-01 showed improvements

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in selected biomarkers and clinical cognitive tests, which support the clinical potential of VS-01 and encourage its further investigation in a Phase 2a study in the target indication of ACLF.

Dr. Meriam Kabbaj, COO and co-Founder of Versantis commented: "The successful completion of Versantis' first-in-human study is another great achievement I am extremely proud of. Beyond the safety of VS-01, this study desacralizes the *i.p.* route of administration in cirrhotic patients and this will certainly open-up new therapeutic avenues bringing a new hope to patients with ACLF. I would like to sincerely thank all of our collaborators and express my gratitude to Prof Trebicka and each of his team member (Mrs Graf-Dirmeier, Mrs Lorenz Pabijan, Dr. Uschner and Dr. Schulz) for their enthusiasm, great commitment to patients and high ethical standards, which will continue to inspire us in our journey."

"We are very encouraged by the compelling results from this Phase 1b, which prove the excellent tolerability profile of VS-01 in a cirrhotic patient population. We look forward to the continued development of this therapy in a Phase 2a study starting early 2022 and hope to soon provide a meaningful new treatment option to patients suffering from acute liver diseases, whom today still face great unmet medical need," added Vincent Foster, CEO and co-Founder of Versantis.

About Decompensated Liver Diseases

Globally 850 million people live with a liver disease and 2 million die every year, primarily due to cirrhosis. Most cirrhotic patients eventually decompensate, requiring hospitalization due to complications, such as hepatic encephalopathy (HE) or acute-on-chronic liver failure (ACLF, a rare disease). As of today, no specific treatments are approved to support such cases, which are associated with high mortality if not medically managed early. By reversing HE and the multi-organ failure cascade of ACLF, VS-01 aims to urgently fill this medical gap.

About Versantis

Versantis is a clinical-stage biotech company focused on the development of orphan drugs in liver and pediatric diseases. Founded by leading scientists from ETH Zurich and industry experts, Versantis is pursuing innovative therapies for the critical care of serious conditions based on its proprietary detoxification platform technology. The company's mission is to bring therapeutic solutions to cirrhotic patients in need by timely support of acute decompensations. Versantis' most advanced program, VS-01, has completed a Phase 1b study. Its clinical development pathway may be streamlined owing to orphan drug designations received by the EMA and FDA, as well as a Rare Pediatric Diseases Designation granted by the FDA. Versantis is headquartered in Zurich, Switzerland. For additional information, visit: www.versantis.ch.

Contact

Versantis AG
Vincent Forster, +41 44 500 8891
info@versantis.ch

Halsin Partners
Mike Sinclair, +44 20 7318 2955
msinclair@halsin.com

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