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Versantis Gets Cash For Toxin 'Undelivery' Product

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INTERVIEWS

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Executive Summary

Emerging Company Profile: CHF16m for Swiss firm that engineers liposomes to capture toxins and protect the organs of patients with acute liver failure.

*Source: Versantis*R-L: REKHA JOHNSON (SENIOR CLINICAL MANAGER), SOPHIE BIGUENET (CMO), VINCENT FORSTER (CEO) AND MERIAM KABBAJ (COO)

Dubbed “undelivery” technology by its
CEO, Versantis is applying liposome technology to protect the organs of patients with acute liver disease and other conditions.

The firm has just raised CHF16m to take its lead product, VS-01, to clinical proof of concept in decompensated liver cirrhosis and acute-on-chronic liver failure. The product is designed to be used as an emergency rescue therapy in hospital to protect the organs of acutely ill patients before they end up on dialysis in intensive care.

Although liposome engineering has been around for 40 years and liposomes containing an acidic medium like Versantis’s are already being used in drug delivery systems, the company is working on a different way of using the technology.

“We took this drug delivery technology and turned it around to develop a new product which will be used for ‘undelivery’: for capturing toxins directly inside the body,” CEO and co-founder Vincent Forster told *Scrip*. Early work was done at ETH Zurich in the Institute of Pharmaceutical Science by Professor Jean-Christophe Leroux and then translated into a prototype product by Versantis.

“We discovered a ground-breaking route of administration, which is this intra-peritoneal route, with supporting fluid which then gives access to this wide surface area of the peritoneum,” Forster explained. The peritoneum is highly vascularized and allows for very rapid exchanges with the blood so “our product is very efficient at rapidly capturing and removing out of the body this excess of toxins.”

The liposomal fluid is administered via the same port and catheter routinely and rapidly inserted on the general ward to drain the ascites, or build-up of fluid in the abdomen, that occurs when the liver starts to fail. The liposomes are engineered to remain in the cavity throughout the period of the treatment, approximately two hours. Then, loaded with the toxins, they are drained out of the cavity through the same catheter.

Company name: Versantis.

Location: Zurich, Switzerland.

R&D Focus: acute care of serious liver conditions and pediatric inborn errors of metabolism.

Founding Date: 2015.

Founders: Meriam Kabbaj, Jean-Christophe Leroux and Vincent Forster.

Employees: Five FTEs.

Financing To Date: Seed funding (2015), CHF4.4m Series A (2017), CHF16m Series B (2019).

Investors: Swisscanto Invest by Zürcher Kantonalbank, Esperante Ventures, investiere, Redalpine HealthEquity, ZürcherKantonalbank Start-up Finance and private investors.

The fact that there are no new chemical entities in the product means it should be considered "extremely derisked as a drug," commented Meriam Kabbaj, chief operating officer and co-founder of the company. "There are no concerns because we are using safe components that have already been used." VS-01 is classified as a drug, not a device, partly because its closest relatives – peritoneal dialysis fluids – are classified as drugs. Also, some metabolism occurs following administration because although systemic exposure is limited, some free components do reach the blood circulation.

The company is launching a Phase Ib trial in which 1-3 liters of VS-01 will be injected into patients' abdominal cavity. The fluid contains "micro-scavengers" – liposomes containing an acidic medium – that rapidly capture and retain toxins (including ammonia, the major toxin present in decompensated cirrhosis, which can damage the brain). The expectation is that the product would be administered once or twice a day over a week to help the patient recover from the toxic stage and protect the brain and other organs from the surge of toxins. As well as ammonia, it captures urinic and hepato-toxins to protect the brain, kidneys and liver.

While many pharmaceutical companies are developing products to treat earlier stages of liver disease, notably non-alcoholic steatohepatitis (NASH) and fibrosis, or at the later stage, compensated cirrhosis, the pipeline is sparse for the end stage of decompensated cirrhosis. "As soon as the patients decompensate, there are literally no drugs to be administered to these patients," Kabbaj underlined. "They are admitted to hospital and when their condition worsens, they eventually have to go to the ICU to undergo dialysis. So this is where we would like to position our drug and give a tool to the physician to efficiently act during this early course of the disease."

“The advantage of the product is we can treat the patient early on, which is key for guaranteeing a clinical benefit,” explained Forster. He noted that another advantage is that the product can remove several toxins at once, providing “multi-organ support.”

Other companies are developing drugs to target specific toxins such as ammonia, or trying to tweak dialysis techniques to make it more applicable to patients with liver disease. “However, both approaches have major disadvantages,” noted Kabbaj. “When targeting only one toxin, it’s impossible to be effective enough to support these patients because they are dying from a multi-organ disease. And the problem with dialysis is that although it is effective, it is initiated very late in the course of the disease. [VS-01] can be implemented early on and it can be as effective as dialysis.”

The company aims to complete a Phase Ib first-in-human trial in the second quarter of 2020, in which it hopes to establish safety and initial indications of efficacy. The trial will be direct to patients and will enroll 12 subjects. Versantis will then conduct a Phase IIa study in about 30 more severely ill patients with acute-on-chronic liver failure, an orphan indication. After that, a Phase IIb confirmatory efficacy study will be conducted.

The latest fundraising will cover the Phase Ib and Phase IIa studies. “We truly believe that at the end of the Phase IIa we will have clinical proof of efficacy in two indications so that may present us with the first exit opportunities,” Kabbaj said. “The other alternative is to sign a partnership or do a series C for the last filing studies for the orphan indications.”

Potential Partners

Big pharma companies already active in the liver disease field have expressed an interest in the technology and “we are already discussing with most of them,” said Forster. “Dialysis companies are also interested because we are very close to what they are developing but also because we are just outside of the ICU and therefore we get traction from both the pharma side and the large medical device companies.”

Versantis has received orphan drug designation for VS-01 in both the US (in acute-on-chronic liver failure) and the EU (in acute liver failure).

Coming up behind VS-01 are additional development plans, including in rare inborn errors of metabolism that lead to toxic accumulation of ammonia. Within 24 hours of birth, babies with such genetic disorders proceed to seizures and coma and, if they survive, most of them have severe neurological problems.

The company is also working on a diagnostic test for measuring ammonia rapidly and specifically – “this is still missing both in the hospital and as a point of care device for the patient,” said Forster.

All of the major investors from the series A round have re-invested into the series B round.

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