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# Versantis raises $16M for liposome-enhanced liver dialysis program

*By Cormac Sheridan, Staff Writer*

DUBLIN – Versantis AG raised CHF16 million (US$16.1 million) in a series B round to progress clinical trials of a liposomal-based fluid in development for eliminating ammonia and other toxic metabolites from the circulation of patients in acute stages of liver failure who are undergoing peritoneal dialysis.

Liver dialysis, unlike standard kidney dialysis, is a high-risk procedure and is only undertaken once patients' liver function has deteriorated to the point where they need intensive care unit (ICU) support. It employs the peritoneum as a natural semipermeable membrane that allows the transfer into the peritoneum of waste products and metabolites that cannot be eliminated by the liver.

The Zurich, Switzerland-based firm has obtained orphan drug designation for the product, VS-01, which comprises a liposome-encapsulated formulation of citric acid. The liposomes, which have a transmembrane pH gradient, act as scavenging vesicles, trapping within their acidic core protonated toxic metabolites that diffuse into the peritoneal fluid from the circulation. The liposome-containing dialysate is then drained out at the end of the procedure through a catheter inserted directly into the abdomen.

"It's amazingly effective at clearing one of the toxins which is extremely neurotoxic – ammonia," Versantis' co-founder and chief operating officer, Meriam Kabbaj, told *BioWorld*. Hyperammonemia or excessive ammonia in the circulation, can cause hepatic encephalopathy, a set of neuropsychiatric abnormalities that occurs in many patients with advanced cirrhosis. "Apart from that we also clear out the other toxins that accumulate in these patients," she said.

Hepatologists have very limited treatment options available before that point. "They don't have any tools to treat them in the ward," CEO and co-founder Vincent Forster told *BioWorld*. "The only cure for these patients is to get a new liver." VS-01 could extend the bridge to transplant – as well as shortening ICU stays – by improving the efficiency and utility of peritoneal dialysis.

Versantis is a spin-out from the Swiss Federal Institute of Technology, Zurich (ETH Zurich), where Forster conducted PhD studies in pharmaceutical sciences. He and co-workers published several papers on the product concept, which was initially positioned as a rescue therapy for drug overdoses. However, confining the liposomes to the peritoneum offers a better safety profile. The liposomes the company employs are large, to ensure that they do not traffic into the circulation.

A preclinical study in rats, reported in the Oct. 15, 2014, issue of *Science Translational Medicine*, reported that only 0.2% of an injected dose of large vesicles were detected the circulation after four hours of dialysis. In the same study, the levels of ammonia were 7.5-fold higher in the peritoneal fluid than in the plasma after just 30 minutes of dialysis. Adjusting the internal pH levels of the liposomes also allowed for the uptake of propionic and isovaleric acids, which can build up in the body of patients with rare congenital disorders.

The company is taking a stepwise approach to clinical development. A phase Ib trial is now underway. It is recruiting 12 patients with early stage decompensated cirrhosis. Safety is the main focus of the study, but it may also pick up preliminary signs of efficacy. A planned phase IIa trial will include about 30 patients – the protocol has not yet been finalized – with hepatic encephalopathy and acute-on-chronic liver failure, a sudden, life-threatening deterioration in liver function. It also plans to include in a subsequent phase IIb trial pediatric patients who develop hyperammonemia as a result of inborn errors of metabolism.

VS-01 could conceivably gain regulatory approval through the device pathway, but the drug approval pathway offers greater flexibility in terms of securing an exit. Device firms typically have to obtain approval and start commercialization before they generate interest from acquirers, Forster said. In addition, the orphan drug designation provides additional incentives in the form of market exclusivity and tax credits. “It’s really an advantage,” he said.

Its potential partners include medical technology firms that develop dialysis equipment as well as pharmaceutical companies focused on less severe liver indications, such as nonalcoholic steatohepatitis. “They already have the sales and distribution channels,” Forster said.

Versantis has raised about $22 million in equity finance since its inception. The lead investor on the present round was the Swisscanto Invest arm of Zürcher Kantonalbank. Other new investors include Esperante Ventures, Investiere and several undisclosed private investors. Existing shareholders Redalpine Healthequity, and Zürcher Kantonalbank Start-up Finance also participated. Robert Schier, of Swisscanto Invest, is joining the company’s board. In addition to Forster and Kabbaj, a PhD level pharmacist with 10 years’ experience at the CRO Celerion, the leadership team includes recently appointed Chief Medical Officer Sophie Biguenet, who has 15 years of big pharma experience, and a senior clinical manager, Rekha Johnson, who has startup and large pharma experience.