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Lindis' Catuvab is designed to remove tumor cells from surgical blood

By Bernard Banga, Staff Writer

BERLIN – Lindis Blood Care GmbH launched a multicenter clinical EU certification study for Catuvab, which is used to eliminate tumor cells from surgical blood. The experiment, dubbed Remove, aims to confirm that Catuvab can reliably remove epithelial cell adhesion molecules (EPCAM)-positive tumor cells from patient blood during cancer surgery.

EPCAM is a tumor marker found in almost all common carcinomas. "With the removal of these tumor cells, it should be possible to safely return the patient's own blood to them during surgery," Franzpeter Bracht, CEO and co-founder of Berlin-based Lindis Blood Care, told *BioWorld*.

The first patients have already been enrolled at trial sites in Germany.

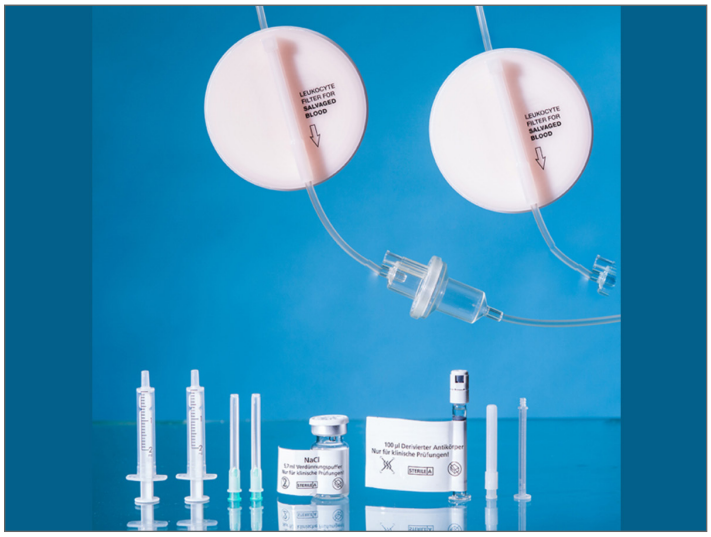
During cancer surgery, donor blood is typically used when massive blood loss occurs. This is the case in half a million oncology procedures worldwide each year. However, transfusing donor blood can lead to various side effects, such as transmission of viruses like hepatitis or cytomegalovirus, immunosuppression, wound infection or even transfusion-related acute lung injury.

5% of blood transfusions use autologous blood

Medical teams often use intraoperative blood salvage (IBS) to reduce or avoid the need for allogenic red blood cell transfusion. Surgeons collect and then return a patient's blood during tumor surgery. Five percent of blood transfusions in the U.S. and some countries in Europe use autologous blood, obtained primarily preoperatively.

"IBS is common in major surgery. However, it is not currently part of the standard of care in cancer surgery because of cancer cells that can be found in the shed blood," said Bracht. Up until now, using autologous surgical blood has only been permitted in cancer surgery in conjunction with radiation, which is available in a limited number of clinics in Europe.

Lindis was formed in 2018 by two biologists, Horst Lindhofer and Franzpeter Bracht. The former invented and developed the first trifunctional antibody initially approved in Europe, Canada and Russia. The latter is a former CEO and COO of several life sciences companies in Germany, including Celonic AG, Glycotype GmbH, Nexigen GmbH and Aplagen GmbH.



Catuvab device for blood management in cancer surgery. Credit: Lindis Blood Care GmbH

"We are developing technology for autologous blood transfusion in cancer patients, which uses the proven trifunctional antibody in combination with our Catuvab device," said Bracht.

Lindis has developed an antibody platform based on a trivalent antibody and using autotransfusion equipment already used in hospitals. The bispecific trifunctional antibody binds tumor cells, including cancer stem cells, via the EPCAM markers. The antibody then induces the bond between cancer cells and immune cells. Resulting cell complexes are removed in two steps: First, during a standard IBS procedure, then through filtration using a leukocyte depletion filter.

"This mechanism of action is purely physical and does not involve any pharmacological, immunological or metabolism action," said Bracht.

The Catuvab kit includes two filters, a buffer, syringes and the antibody. Each kit is capable of cleaning up to three liters of blood. The procedure makes it possible to transfuse autologous erythrocyte concentrate back into the patient.

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In vitro data and ex vivo pilot studies

Lindis started developing Catuvab by collecting data regarding its ability to remove EPCAM-positive tumor cells form blood, including cancer stem cells. It has already provided proof-of-concept both in vitro and in an initial clinical study on patients.

The in vitro study was completed in 2019. Blood drawn from volunteers was first spiked with tumor cells and then treated with Catuvab and a standard IBS device. The final erythrocyte concentrate was then screened for tumor cells and residual antibody following the leukocyte depletion step. "The results show very low antibody concentration; no residual tumor cells were detected in the final erythrocyte concentrate," said Bracht.

In 2020 the company carried out an exploratory study at a German university in which the process was used to treat intraoperative blood from 15 patients during cancer surgery. Tumor cells remaining in the erythrocyte concentrates were counted, along with residual antibodies and other safety parameters. "Here, too, no residual EPCAM-positive tumor cells were found after using Catuvab in this ex vivo pilot study. Publication is imminent," said Bracht.

An international study that enrolled up to 110 patients

The Remove multicenter, international clinical validation study includes up to 110 patients. Markus Heiss, head of visceral surgery at the Cologne-Merheim campus at Witten/Hedecke University Hospital, is principal investigator. Disease indications include lung, stomach, pancreatic, colon and ovarian cancers and endometriosis. The primary endpoint is to demonstrate depletion of EPCAM-positive tumor cells.

"Based on the positive data from our exploratory study, this study should lay the ground for CE marking in the EU," said Bracht.

Top-line results are expected in the first half of 2022.

Lindis has financial support from the North Rhine-Westphalia and Brandenburg regions in Germany, through High-Tech Gründerfonds Management GmbH in Berlin, Brandenburg Kapital GmbH in Potsdam and ProFIT Brandenburg, the region's economic development agency.

"We are actively seeking international licensing partners to support our next efforts outside of Europe," said Bracht.