LINDIS BLOOD CARE

Press Release

Lindis Blood Care Announces Publication of Clinical Pilot Study Results Successfully Highlighting the Potential of CATUVAB® in the Removal of Tumor Cells from Surgical Blood in Peer-Reviewed Journal

Hennigsdorf, Berlin, Germany – November 10, 2021.

- Study results in 16 cancer patients undergoing abdominal tumor resection have shown efficacy and feasibility with no residual malignant cells detected in the final erythrocyte concentrates after CATUVAB® procedure
- Further safety parameters promising: pro-inflammatory cytokines IL-6 and IL-8 released during surgery significantly lowered (28-fold and 52-fold), only uncritical residual amount of the antibody used detected
- Confirmatory study 'REMOVE' initiated; top-line results expected in H1 2022
- CATUVAB® is designed to reliably remove tumor cells from surgical blood during cancer surgery, thereby, not only avoiding the typical risks associated with donor blood but also decreasing the usage thereof

Lindis Blood Care, a company that aims to implement a new gold standard for blood management during cancer surgeries with its medical device CATUVAB® for the removal of tumor cells from surgical shed blood, is pleased to announce that the clinical results from its ex-vivo pilot study with CATUVAB® are now published in the international peer-reviewed journal *BMC Anesthesiology.* The publication *"Removal of EpCAM-positive tumor cells from blood collected during major oncological surgery using the Catuvab device - a pilot study"* can be accessed online at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8555247/.

The study in 16 patients undergoing abdominal tumor resection investigated the feasibility, efficacy and safety aspects of the newly developed CATUVAB® procedure. CATUVAB® consists of a trifunctional antibody, that aggregates the tumor cells and lymphocytes, and a leukocyte depletion filter (LDF). The procedure is applied extra-corporally to the intraoperative blood during oncological high blood loss surgery and the treated blood is then re-transfused back to the patient in a timely manner. CATUVAB® is designed to remove EpCAM (epithelial cell adhesion molecule)-positive tumor cells from the patient's blood, thus, enabling risk free re-transfusion of autologous blood during tumor operations in the context of standard IBS (intraoperative blood salvage) procedures. Due to concerns for potential metastasis caused by residual tumor cells, that are released during surgery, these procedures are usually a contraindication to the usage of IBS procedures.

Results of the study showed, that after the CATUVAB® procedure, no malignant cells were detected in the final erythrocyte concentrates. Further safety parameters under investigation were also promising: the concentration of the pro-inflammatory cytokines IL-6 and IL-8, released during surgery, were significantly lowered in mean by the 28-fold and 52-fold, respectively. Residual levels of the antibody applied were detected in 8 of 16 of the final EC products at a considerably decreased and uncritical residual amount (37 ng in mean). This pilot study showed that it is feasible to implement the CATUVAB® procedure easily into the blood collection & processing procedure.

Univ.-Professor Kai Zacharowski, MD PhD ML FRCA Director of the Department of Anaesthesiology, Intensive Care Medicine and Pain Therapy at the University Hospital Frankfurt, explained: “The preliminary study results have demonstrated efficacy and feasibility of CATUVAB® in the reinfusion of autologous erythrocyte concentrates produced by an IBS device during oncological high blood loss surgery. With the reliable removal of the tumor cells, the medical device shows great potential to safely return the patient's own blood to them during surgery and, by doing so, avoid typical risks associated with donor blood supply, including suppression of the immune system and potentially increased tumor recurrence rates.”

Dr. Franzpeter Bracht, founder and Managing Director of Lindis Blood Care, commented: “Except for radioactive irradiation there is currently no approved product available on the market, that reliably eliminates the risk of contamination with cancer cells with metastasizing potential during autologous blood transfusion in oncological surgeries. An effective and easy-to-implement method is urgently needed to avoid typical risks associated with allogeneic red blood cell transfusions and decrease the usage of donor blood. CATUVAB® has the potential to set the new ‘gold standard‘ in oncological blood management by combining current filter technologies available at nearly all hospitals with our trifunctional antibody to reliably remove cancer cells from intraoperative blood. We are very much looking forward to further develop this promising new product.”

A confirmatory open-label, multicenter clinical study which will enroll up to 110 patients, has been started to validate the initial findings. Top-line results are expected in H1 2022.

With positive results from the confirmatory study and receipt of the CE mark, CATUVAB® would be the first product that could be used safely and cost-effectively for patient blood management in cancer surgeries. CATUVAB® can be used in combination with machine autotransfusion devices, which are part of the technical equipment available at nearly all hospitals. As EpCAM is a tumor marker that is expressed by a wide spectrum (> 90%) of carcinomas, the procedure is relevant for a large number of oncological surgeries.

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About Lindis Blood Care:
Lindis Blood Care is a medical technology company developing the medical device CATUVAB®. CATUVAB® is used to remove EpCAM-positive tumor cells from surgical blood and is thus designed to enable the use of MAT (machine autotransfusion technology), which is already in applied in non-oncological surgeries broadly today, for the re-transfusion of surgical shed blood in tumor surgeries as well.

During cancer surgeries, donor blood is typically used when large volume blood loss occurs. This is the case for about half a million oncological procedures worldwide, each year. However, the transfusion of donor blood can result in numerous serious side effects and increased tumor recurrence rates. In future, such side effects could be reduced by re-transfusing the patient’s own blood after it being treated with CATUVAB®, In cancer surgeries, the collection and return of surgical blood during an operation (intraoperative blood salvage) with the help of MAT devices, which is standard procedure for many other surgeries, cannot be applied routinely, since tumor cells are often released into the patient’s blood during the surgery. In this case the patient’s blood must not be re-transfused due to the risk of metastasis. That is precisely the point CATUVAB® targets. It consists of a trifunctional antibody and a filter that enables tumor cells to be removed reliably from surgical blood using the standard IBS procedure. The product and process can be integrated easily into everyday clinical practice and become part of contemporary ''patient blood management''.
www.lindis-bloodcare.com

LINDIS BLOOD CARE

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