LINDIS BLOOD CARE

Press Release

Lindis Blood Care Initiates Multicenter Clinical EU Certification Study REMOVE with CATUVAB® to Eliminate Tumor Cells from Surgical Blood

Hennigsdorf, Berlin, Germany - March 18, 2021.

- Based on the positive data from an exploratory study, the confirmatory study 'REMOVE' was initiated and will form the basis for CE marking in the EU
- First patients have already been enrolled; top-line results expected in H1 2022
- CATUVAB® is designed to reliably remove tumor cells from surgical blood during cancer surgery, thereby avoiding the typical risks associated with donor blood

Lindis Blood Care, a company that aims to revolutionize blood management during cancer surgeries with its medical device CATUVAB® for the removal of tumor cells from surgical shed blood, today announced the start of its multicenter study REMOVE. The study is intended to confirm the positive results of a preliminary exploratory study and thus lay the basis for European CE certification as a medical device. First patients have already been enrolled at trial sites in Germany.

The confirmation study, which will enroll up to 110 patients, is designed to confirm that CATUVAB® is for the first time able to reliably remove EpCAM (epithelial cell adhesion molecule)-positive tumor cells from patient blood during cancer surgeries. EpCAM is a tumor marker that can be found on 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 the surgery. By doing so, typical risks associated with donor blood supply, including suppression of the immune system and potentially increased tumor recurrence rates, could be avoided. Until now, the use of autologous (patient's own) surgical blood has only been permitted in cancer surgeries in combination with radiation, which is available in a limited number of clinics. Otherwise, the risk of metastasis from tumor cells being released into the blood during the procedure is assessed as too high. There is currently no approved product that reliably eliminates this risk.

Univ.-Prof. Dr. Dr. med. Kai Zacharowski, ML FRCA Director of the Department of Anaesthesiology, Intensive Care Medicine and Pain Therapy at the University Hospital Frankfurt, explained: "I am pleased to continue to be involved in the clinical development of CATUVAB®, as I believe this approach has the potential to make a significant contribution to patient blood management during cancer surgeries. Blood is a precious and scarce resource and we urgently need new concepts with which we can improve the treatment outcomes for our patients and at the same time sustainably use this resource."

Prof. Dr. Markus M. Heiss, FACS, Head of Visceral Surgery at the University Hospital Witten / Herdecke, Cologne-Merheim location and Head of the clinical trial, continued: "This is an important step as we hope to improve the side effect profile, especially in the case of invasive cancer surgeries, and ease patient recovery. A reliable way to use autologous blood in such procedures would be a real innovation in an area we have not seen significant technological advances for many years."

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Lindis Blood Care's approach has provided proof-of-concept both in vitro and in an initial clinical study with 15 patients. The data showed that no tumor cells could be detected in the surgical blood treated with CATUVAB®. Detailed results of this pilot study will be published in an international peer-reviewed journal.

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. It consists of a trifunctional antibody that aggregates the tumor cells and lymphocytes as well as a filter and can be used in combination with machine autotransfusion devices, which are part of the technical equipment available at nearly all hospitals.

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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 with the use of MAT (machine autotransfusion) technology, which is generally used today to re-transfuse surgical shed blood in non-oncological procedures.

During cancer surgeries, donor blood is typically used when large volume blood loss occurs. This is the case for around 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. Such side effects could be reduced in the future with the use of CATUVAB® and the potential re-transfusion of the patient's own blood. In cancer surgeries, the collection and return of surgical blood during an operation (autologous blood transfusion) with the help of MAT devices, which is standard procedure for many other surgeries, cannot be applied, since cancer 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 possibility of metastasis. This is where CATUVAB® comes in. It consists of a trifunctional antibody and filter that enables tumor cells to be removed reliably from surgical blood using the standard MAT 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

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