LINDIS BLOOD CARE

Press Release

Lindis Blood Care Announces Positive Top-Line Results from Clinical Certification Study REMOVE with CATUVAB® to Enable Autologous Blood Transfusions in Cancer Surgeries

- CATUVAB® procedure enables highly effective removal of malignant cells from intraoperative blood. All clinical endpoints met with high statistical significance.
- Convincing safety profile supports use of CATUVAB® during high blood loss cancer surgeries.
- Following these positive results, Company has initiated process to receive CE Mark in Europe and FDA conformity in the US.

Hennigsdorf, Germany – 22 April, 2024.

Lindis Blood Care, a company aiming to set a new standard for blood management during cancer surgeries with its medical device CATUVAB®, announced today excellent top-line results from the REMOVE certification study, a confirmatory open-label, multicenter clinical study, that enrolled more than 130 patients to assess CATUVAB® for use during intraoperative blood salvage (IBS) procedures in cancer surgeries. Data showed that CATUVAB® was safe and effective, meeting all primary and secondary endpoints. The data were presented during the NATA24 Annual Symposium in Bologna on April 19, 2024. Detailed results of this study will be submitted for publication to an international peer-reviewed journal.

The study reported on 119 evaluable patients, of which 61 had tumor cells in the intraoperative blood and 80 received a retransfusion of their own blood after the CATUVAB® procedure. To determine efficacy, the primary endpoint analysis investigated the presence of tumor cells in intraoperative blood and their removal in the erythrocyte concentrate (EC). In all 61 patients where tumor cells were found in the blood salvaged, tumor cells were reliably removed and the primary endpoint was met with a high statistical significance.The secondary endpoints, which covered safety criteria, e.g. reduction of cytokines which are found in intraoperative blood due to the trauma of surgery, were also met with high statistical significance.

Dr. Franzpeter Bracht, founder and Managing Director of Lindis Blood Care commented: “We are extremely pleased with the outcome of the REMOVE clinical trial, where CATUVAB® demonstrated its capability to reliably remove cancer cells from salvaged blood during high blood loss surgeries. The presented results cement CATUVAB®’s promising position as the first medical device designed for this procedure and could redefine the protocols of intraoperative blood salvage in cancer surgeries. Engineered for easy integration within the existing hospital routines, CATUVAB® offers a cost-efficient solution, addressing the current limitations and transforming patient blood management practices. We are now preparing for market authorization in both Europe and the US.”

Professor Patrick Meybohm, MD FESAIC Head of the Department of Anesthesiology, Intensive Care, Emergency and Pain Medicine at the University Hospital Würzburg, explained: “These outstanding results confirm what we saw during the PILOT study. The synergy between the powerful trifunctional antibody (catumaxomab) and leukocyte depletion filter allows CATUVAB® to efficiently bind to and remove tumor cells from intraoperative blood via the general tumor marker EpCAM, eliminating the risk of transfusing blood products with metastasizing capabilities back to patients.”

Professor Kai Zacharowski, MD PhD ML FRCA FESAIC Director of the Department of Anaesthesiology, Intensive Care Medicine and Pain Therapy at the University Hospital Frankfurt further highlighted: "CATUVAB® has the potential to significantly improve blood management during cancer surgeries. Enabling autologous blood transfusions for these patients avoids the risks associated with allogeneic blood donations, such as immunosuppression, potentially increased tumor recurrence rates and an increased number of operation wound infections. Such a procedure would be a real innovation in an area, we have not seen significant technology advances for many years."

REMOVE was one of the largest studies to date assessing a medical device for the removal of tumor cells from intraoperative blood during high blood loss cancer surgeries. CATUVAB® is designed to reliably remove cells from EpCAM (epithelial cell adhesion molecule)-positive tumors from the blood of cancer patients. EpCAM is a tumor marker that can be found on almost all common carcinomas such as ovarian, colon, gastric, prostate, lung and bladder cancer.

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About CATUVAB®

CATUVAB® is the first medical device intended to optimize the intraoperative blood salvage (IBS) procedure used in cancer surgery. It is designed to reliably remove cancer cells from the erythrocyte concentrate (EC) collected during the procedure. The resulting tumor cell-depleted EC can then be re-transfused to the patient without risk of (residual) tumor cell contamination and metastasis. It relies on a trifunctional, bispecific antibody that binds to the general tumor marker EpCAM, present in almost all carcinomas. CATUVAB® forms cell complexes between tumor cells and immune cells, such as lymphocytes and monocytes. These complexes can then be removed via a 2-step approach: centrifugation during standard IBS procedure followed by filtration with a Leukocyte Depletion Filter (LDF). CATUVAB® is easy to integrate into standard IBS procedures and can clean up to 3 liters of intraoperative blood in a safe and effective manner. The device's regulatory approval is ongoing in Europe and the FDA submission is already planned.

About Lindis Blood Care:

Lindis Blood Care is a medical technology company founded by Dr. Horst Lindhofer and Dr. Franzpeter Bracht developing the medical device CATUVAB®. CATUVAB® is used to remove EpCAM-positive tumor cells from surgical blood with the use of IBS (intraoperative blood salvage) technology, which is generally used today to re-transfuse surgically 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 including immunosuppression of the recipient 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 IBS 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 IBS procedure, as shown in the REMOVE certification study. The product and process can be integrated easily into everyday clinical practice and can become part of contemporary "patient blood management".

Lindis Blood Care's success has been facilitated by funding from High-Tech Gründerfonds and Brandenburg Kapital, the venture capital arm of the investment bank of the State of Brandenburg, as well as several private investors.
www.lindis-bloodcare.com

LINDIS BLOOD CARE

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