

Press Release**Lindis Blood Care Announces Last Patient Out in Multicenter Clinical Certification Study REMOVE with CATUVAB® to Eliminate Tumor Cells from Surgical Blood**

Hennigsdorf, Berlin, Germany – December 20, 2023.

Lindis Blood Care, a company aiming to set a new standard for blood management during cancer surgeries with its medical device CATUVAB® for the removal of tumor cells from surgical shed blood, today announced that the last patient in its certification study REMOVE has successfully completed the trial. Top line results are expected in Q1 2024.

REMOVE, a confirmation open-label multicenter clinical study, enrolled 130 patients being one of the largest studies assessing a medical device for the removal of tumor cells in an intraoperative blood salvage (IBS) procedure. CATUVAB® is designed to reliably remove cells from EpCAM (epithelial cell adhesion molecule)-positive tumors from patient blood during cancer surgeries. EpCAM is a tumor marker that can be found on almost all common carcinomas such as ovarian-, colon-, gastric-, prostate-, lung and bladder cancer. With the removal of these tumor cells, it is possible to safely return the patient's own blood to them during high blood loss surgery, thereby avoiding the various risks associated with donor blood including infection with untested virus, immunosuppression, transfusion related lung injury and increasing wound infections by a factor of 3-5. The procedure was applied extracorporeally during oncological surgery and the treated intraoperative blood was then re-transfused back to the patient as an erythrocyte concentrate in a timely manner.

Dr. Franzpeter Bracht, founder and Managing Director of Lindis Blood Care commented: "We are pleased to announce the completion of our confirmatory study, which represents an important milestone towards certification of our device and brings us one step closer to making CATUVAB® and autologous blood transfusion available to cancer patients. We look forward to reviewing the results and anticipate, we could make a significant contribution to patient blood management during cancer surgeries."

Dr. Horst Lindhofer, founder and Managing Director for Scientific Affairs of Lindis Blood Care added: "Blood is a precious and scarce resource. Being able to use a cancer patient's own blood in the operation room by avoiding the risk of metastases from remaining tumor cells would be a much needed transformation in the patient blood management landscape."

Expecting positive results from the confirmatory study REMOVE and going for EU Medical Device Regulation and FDA conformity as well as market authorization, CATUVAB® would be the first product that could be used safely and cost-effectively for patient blood management in cancer high blood loss surgeries. This procedure aims to be an easy-to-implement method that combines trifunctional antibody that aggregates the tumor cells and lymphocytes with current filter technologies and intraoperative blood salvage devices 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 IBS (intraoperative blood salvage) 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 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. The product and process can be integrated easily into everyday clinical practice and 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.

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