Press Release

LINDIS Biotech Presented Encouraging Data from High Risk-Non-Muscle-Invasive Bladder Cancer Patients Treated with Trifunctional Antibody CATUMAXOMAB at EMUC22

- Results from Phase I dose escalation trial of anti-EPCAM/CD3 presented at the EMUC 2022 congress demonstrated encouraging preliminary efficacy and excellent safety and tolerability profile, treatments at the recommended dose of 70 µg have been initiated
- Data showed that 100% of patients that completed treatment in the 70 µg and 100 µg dose groups achieved a complete remission as best response with no recurrence throughout the period of follow-up
- High risk and very high risk NMIBC is a type of bladder cancer, that is particularly challenging to tackle as patients experience a high risk of recurrence and progression; current standard of care BCG comes with significant side effects, high dropout rates, while rates of recurrence and progression remain substantial

Munich, Germany, November 14, 2022 - LINDIS Biotech GmbH, a biopharmaceutical company with a proprietary multi-specific antibody platform and an advanced development pipeline with three clinical product candidates in immuno-oncology, announced that encouraging data from all three dose groups of the dose escalation part of its ongoing Catunibla Phase I trial (Catunibla; EUDRACT number: 2019-002850-22; clinicaltrials.gov: NCT04819399) with the trifunctional anti-EPCAM/CD3 monoclonal antibody CATUMAXOMAB for treatment of non-muscle-invasive bladder cancer (NMIBC) were presented at the 14th European Multidisciplinary Congress on Urological Cancers (EMUC22) November 10-13, 2022 in Budapest, Hungary. Based on the positive results demonstrating an excellent safety and tolerability profile as well as preliminary efficacy, expansion at the recommended dose of 70 µg per instillation were initiated.

Data from all three dose levels (50 µg, 70 µg and 100 µg) of the Phase I dose escalation confirmed the findings from the two lower dose levels that were announced previously (see press release). Consistent with previous findings, CATUMAXOMAB was well tolerated, and there was no dose limiting toxicity. Treatment emergent adverse events (AEs) were only of grade 1-2, no serious adverse events (SAEs) were observed. Results showed that all patients included in level 2 and 3 dose groups of 70 µg and 100 µg of the dose escalation part achieved a complete remission (7/7 CR) as best response following first transurethral resection of the bladder tumor (TUR-B) and

CATUMAXOMAB treatment. The median durable CR up to date is 9.5 months (range 7.3-19.9 months). Remarkably, these CRs contained 4/5 diagnosed CIS (carcinoma in situ) which cannot be removed by surgery and therefore can be attributed to Catumaxomab in situ antitumor efficacy.

“We are pleased to see the progression of the Catunibla study into its next stage. Our previously released compassionate use data, as well as the positive results and follow-up data from the dose escalation are strongly encouraging. While the data are still early, it is remarkable that in addition to Catumaxomab being safe and well tolerated, patients in all three dose groups showed significant clinical benefits, including ongoing remissions in all patients that completed treatment at dose level 2 and 3. We are excited to further elucidate CATUMAXOMAB’s potential to become a safe, effective and well tolerated therapy that could have a major impact on improving patient care in this high need indication,” **commented Dr. Horst Lindhofer, founder and CEO of LINDIS Biotech and inventor of CATUMAXOMAB.**

During its last review, the Data Safety Monitoring Board identified no safety concerns and recommended the trial to continue at the dose of 70 µg. The observed strong reduction of urinary EpCAM positive cells during and after CATUMAXOMAB treatment suggests that the trifunctional bispecific EpCAM targeting antibody binds and efficiently kills EpCAM-positive bladder cancer cells in urine milieu. This shows considerable potential to extend the tumor-free period within treatments and consequently to significantly reduce the number of BCG instillations required, the current standard therapy with well-known severe side effects.

Dr. med. Ralph Oberneder, Chief Director of Urological Clinic Munich-Planegg, continued: “The unique characteristic of CATUMAXOMAB as a bispecific monoclonal antibody enables the mediation of antibody-dependent cellular cytotoxicity against human epithelial tumor cells including bladder cancer. The data obtained in the dose escalation phase present legitimate grounds for hope that developing the antibody CATUMAXOMAB will lead to a more effective, tolerable, and in particular specific alternative to BCG or combination therapy for the treatment of NMIBC. This would be a huge step forward in an area with practically no recent drug innovation. I am very much looking forward to further develop this promising candidate in this indication.”

The Catunibla trial evaluates the safety and potential initial efficacy signals of the intravesical administration, i.e., administration via a catheter directly into the bladder, of anti-EpCAM/CD3 antibody CATUMAXOMAB as a potential first in class immuno-oncology treatment option for patients with NMIBC of high risk of progression. The objective of developing this drug candidate in this indication is to reduce the rate of

radical bladder removal (cystectomy) as well as to decrease recurrence and progression rates.

Non-Muscle-Invasive Bladder Cancer (NMIBC) – an indication lacking recent drug innovation and for which current standard of care correlates to significant side effects

NMIBC is a cancer indication with an extremely high burden for both patients and the healthcare system as its tumors tend to be multifocal, recur chronically and usually are resistant to chemotherapy. High risk or very high risk NMICB is a type of bladder cancer, that is particularly challenging to tackle, as patients experience an increased risk of recurrence and progression. The current standard of care - after surgical removal of tumor - is direct instillation of BCG (Bacille Calmette Guerin) into the urinary bladder, which is performed repeatedly over a period of up to 3 years. This therapy, however, is characterized by high tumor recurrence rates (60-70%) and considerable side effects, which require close monitoring and continuous treatment. Should this therapy fail, patients with high-risk NMIBC tumors must often resort to cystectomies in order to prevent the tumor from progressing, which is an invasive surgery that has a significant impact on their quality of life. The BCG therapy itself often causes a painful, nonspecific cystitis, which is associated with a high dropout rate and severe side effects.

More Information:

About CATUMAXOMAB

Catumaxomab is a bispecific trifunctional antibody that binds directly to the tumor cell with one of its binding sites and activates two essential components of the immune system with the other binding sites: T cells and Fc-gamma receptor positive cells (macrophages etc.). The antibody recognizes and binds to all EpCAM-positive tumor cells, including critical cancer stem cells and all CD3-positive T cells. The EpCAM marker is present on almost all carcinomas and, therefore, is a promising approach for targeted cancer treatment. In 2009, catumaxomab was approved in Europe for the indication of malignant ascites (the buildup of fluid containing cancer cells in the space around the organs in the abdomen) and has proven its safety and anti-tumor efficacy in the clinic.

About LINDIS Biotech GmbH

LINDIS Biotech GmbH, a biopharmaceutical company with a proprietary multi-specific antibody platform and an advanced development pipeline with three clinical product candidates in immuno-oncology, was founded in 2010 by Dr. Horst Lindhofer, inventor of the Triomab® platform. LINDIS Biotech is the only company that owns a technology

which combines extremely effective tumor cell destruction with a patient-specific vaccination based on trifunctional bispecific antibodies. The Company is therefore ideally positioned in the area of cancer immunotherapeutic agents. As the first product to emerge from this platform and a breakthrough in the development of bispecific antibodies, catumaxomab was approved in 2009 in Europe under the name Removab® for the indication of malignant ascites and has proven its safety and anti-tumor efficacy in the clinic.

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