Press Release

LINDIS Biotech Announces Online Publication of Abstract on Trifunctional Antibody CATUMAXOMAB for the Treatment of High-Risk Non-Muscle-Invasive Bladder Cancer at the ASCO 2022 Annual Meeting

Observed Preliminary Efficacy and Safety together with High Complete Remission Rate Strengthens Evidence of Therapy's Potential

Martinsried, Germany, June 1, 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, announces the online publication of an abstract presenting interim data from the Company's Catunibla Phase I dose escalation trial with CATUMAXOMAB at the American Society of Clinical Oncology (ASCO) Annual Meeting. The abstract is available at: https://meetings.asco.org/abstracts-presentations/209733/video**.**

The abstract reports clinical data from the first two of three cohorts included in the dose escalation of the ongoing Catunibla trial, assessing the safety and effectivity of trifunctional anti-EpCAM/CD3 antibody CATUMAXOMAB as a potential first in class immuno-oncology treatment option for Non-Muscle-Invasive Bladder Cancer (NMIBC). Seven patients with newly diagnosed high risk NMIBC received six weekly intravesical instillations of CATUMAXOMAB at 50 and 70 µg, respectively, after a first transurethral resection of the bladder tumor (TUR-B). Subsequently, tumor status was assessed again in a second look TUR-B and patients received standard of care adjuvant instillation therapy with Bacillus Calmette–Guérin (BCG) if they did not decline.

The data showed that all patients in the higher dose group (70 µg) achieved a complete remission as best response following first TUR-B and CATUMAXOMAB treatment alone with no recurrence over length of follow-up (1 year). Remarkably, carcinomas in situ observed at first TUR-B were no longer detectable in three of five patients following CATUMAXOMAB treatment. The 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. It shows considerable potential to extend the tumor-free period within treatments in these patients and consequently significantly reduce the number of BCG instillations required, the current standard therapy with well-known severe side effects.

CATUMAXOMAB was well tolerated, and there was no dose limiting toxicity. No instillation-related reactions were observed and proinflammatory cytokines typically remained below lower limit of quantification (LLQ). Due to the specific anatomy of the bladder and direct administration of the treatment via urinary catheter, CATUMAXOMAB was not detectable in the systemic circulation. Human anti-mouse-antibodies (HAMA) responses were weak, transient in nature and not associated with any adverse events

Dr. med. Felix Albert, Senior Physician at Urological Clinic Munich-Planegg where the trial is conducted and first author, said. "The achievement of complete remissions following CATUMAXOMAB treatment, as demonstrated in the first two dose cohorts, strengthens the evidence of the therapy's potential. We were especially pleased to see that the *in Situ* carcinomas identified during first TUR-B were no longer detected in a follow-up resection in three patients after treatment with CATUMAXOMAB. Due to their diffuse location in the tissue, these types of tumors cannot be surgically removed, and usually require instillation therapy with BCG with all its well-known adverse side effects. This treatment was safe and easy to administer, and these initial results solidify our belief, that CATUMAXOMAB could significantly improve clinical outcomes for patients with NMIBC who have limited treatment options."

Dr. Horst Lindhofer, founder, and CEO of LINDIS Biotech and inventor of CATUMAXOMAB, commented: "We are pleased with the inclusion of our clinical data in such a high-profile conference. The observed clinical activity and safety is highly encouraging and underscores the earlier results with long lasting remissions we have seen on a named-patient basis. I very much look forward to sharing the complete data set of the dose escalation Phase I Catunibla trial at further scientific conferences."

Abstract information

Title: Intravesical therapy with the trifunctional anti-EpCAM/CD3 bsAb Catumaxomab is well tolerated and shows encouraging preliminary efficacy in patients with high-risk NMIBC (CATUNIBLA phase I trial).
Abstract #: 209733
Link: https://meetings.asco.org/abstracts-presentations/209733/video

More Information:

About Catunibla

Catunibla (EUDRACT number: 2019-002850-22; clinicaltrials.gov: https://clinicaltrials.gov/ct2/show/NCT04799847) is a Phase I dose escalation study that aims to determine the safety and efficacy dose of the trifunctional antibody CATUMAXOMAB for treatment of high-risk non-muscle-invasive bladder cancer (NMIBC). Patients were divided into cohorts, each receiving a different dose of CATUMAXOMAB 6x weekly, via a catheter directly into the bladder.

About NMIBC

Bladder cancer is the 9th leading type of cancer worldwide with 430,000 new cases and about 165,000 deaths occurring every year. Advanced and metastasized bladder cancer remains a fatal disease. However, a majority of about 75% of diagnosed bladder cancers are local and non-muscle-invasive. NMIBC is a cancer indication with an extremely high burden for both patients and the healthcare system because its tumors tend to be multifocal, recur chronically and usually are resistant to chemotherapy. 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.

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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