Press Release

LINDIS Biotech Reports Successful Initiation of Clinical Phase I Dose Escalation Study with the Trifunctional Antibody CATUMAXOMAB for Treatment of Non-Muscle-Invasive Bladder Cancer

- **First dose cohort successfully treated**
- **Study to evaluate safety and initial signals of efficacy in up to 30 patients; results of an interim analysis anticipated in fall 2021**
- **CATUMAXOMAB would be the first specific immunotherapy for non-muscle-invasive bladder cancer, an indication with an extremely high unmet medical need**

Munich, Germany, April 13, 2021 - 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, today announced the successful initiation of its clinical Phase I dose escalation study (Catunibla; EUDRACT number: 2019-002850-22, clinicaltrials.gov: NCT04819399) with the trifunctional antibody CATUMAXOMAB for treatment of non-muscle-invasive bladder cancer (NMIBC). A few days ago, the first dose cohort in the Catunibla study was successfully completed with the treatment of the third patient.

The study, which will include a total of up to 30 patients at several centers across Germany, will evaluate the safety and potential initial efficacy signals of the intravesical administration of CATUMAXOMAB, i.e., administration via a catheter directly into the bladder. The objective for developing this drug candidate in the indication NMIBC is to reduce the rate of radical bladder removal (cystectomy) as well as decrease recurrence and progression rates. CATUMAXOMAB is a bispecific trifunctional antibody that has already been 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.

Dr. Horst Lindhofer, founder and CEO of LINDIS Biotech and inventor of CATUMAXOMAB, commented: “I am very pleased that, after the remarkable clinical successes in malignant ascites, we can now use our antibody in another indication with a high unmet medical need. In contrast to the current standard treatment with BCG (Bacillus Calmette-Guerin), CATUMAXOMAB can generate a targeted anti-tumor immune response, as the bispecific antibody binds directly to the tumor cell with one binding site. We were extremely encouraged by the initial results from preliminary tests, which showed that we could achieve a real difference in patient treatment for this indication.”

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 is direct instillation of BCG (Bacille Calmette Guerin) into the urinary bladder, which is performed repeatedly over a period of up to 3 years. 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.

Dr. med. Ralph Oberneder, Chief Director of Urological Clinic Munich-Planegg, continued: "There is justified hope that by developing the antibody CATUMAXOMAB, we will have a more effective and tolerable alternative to BCG therapy in the future for the treatment of NMIBC. This would greatly improve patient care and represent a huge step forward in an area with practically no recent drug innovation."

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 macrophages (scavenger cells). 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 is therefore 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. In 2017, LintonPharm, partner of LINDIS Biotech, in-licensed four Triomab® antibodies from LINDIS Biotech for further development and commercialization in the Asia-Pacific region. In early February 2021, LintonPharm, has been authorized by China Health Authority (NMPA) to proceed with a Phase 1/2 clinical trial (clinicaltrials.gov: NCT04799847) of CATUMAXOMAB for the same indication (non-muscle-invasive bladder cancer), which represents another great opportunity to evaluate the therapeutic potential of CATUMAXOMAB in patients with NMIBC.

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