Press Release

LINDIS Biotech receives Positive CHMP Opinion for KORJUNY® (catumaxomab) in the European Union

- Upon authorization by the European Commission, KORJUNY® will be the only drug approved and available for the intraperitoneal treatment of malignant ascites in adults with epithelial cell adhesion molecule (EpCAM)-positive carcinomas
- Data demonstrate that the efficacy of the treatment with paracentesis and catumaxomab was statistically significantly superior to that of paracentesis alone in terms of puncture-free survival and time to first need for therapeutic ascites puncture
- EU marketing authorization expected end of 2024

Munich, Germany, October 21, 2024 - LINDIS Biotech GmbH, a biopharmaceutical company with a proprietary multi-specific antibody platform and an advanced development pipeline in immuno-oncology, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the approval of trifunctional anti-CD3 x anti-EpCAM antibody (trAb) KORJUNY® (catumaxomab) for the intraperitoneal treatment of malignant ascites (MA) in adults with EpCAM-positive carcinomas who are not eligible for further systemic anticancer therapy.

The positive opinion from the CHMP will now be reviewed by the European Commission (EC) which renders the final decision on approval. The EC's decision will be applicable to all member states of the European Union, plus Iceland, Liechtenstein, and Norway. If approved, KORJUNY® would become the only drug approved for the specific and cancer-directed treatment of malignant ascites, an abnormal accumulation of fluid in the peritoneal cavity that commonly arises from advanced-stage cancers, particularly those of ovarian, gastric, colorectal, pancreatic, prostate, lung and endometrial origin.

"Our experience demonstrates the profound impact catumaxomab can have on patients facing this critical condition. We are therefore thrilled that the CHMP has recommended approval of catumaxomab for the indication of malignant ascites and about the opportunity to bring this pioneering therapy back onto the market," **commented Dr. Horst Lindhofer, Chief Executive Officer of Lindis Biotech**. "We very much look forward to the formal approval of this treatment and to further develop the potential of this unique immunotherapy in other indications with high unmet medical need, such as bladder cancer."

The CHMP recommendation for KORJUNY®, dated October 18, 2024, is supported by data from a Phase II/III study (IP-REM-AC-01), a large randomized, international, multi-center clinical study which demonstrated a statistically significant improvement of the primary endpoint puncture-free survival. Patients receiving KORJUNY® had a

four-fold increase in puncture-free survival over therapy with puncture alone, still the most common intervention and standard therapy in chemotherapy-refractory MA patients [Heiss et al., 2010].

Prof. Carsten Bokemeyer, Director of the Department of Medical Oncology and Hematology at the University of Hamburg, UKE stated: "Ascites is a typical complication in patients with intensively pre-treated and advanced gastrointestinal malignancies - particularly gastric cancer. The clinical management of malignant ascites remains a distressing problem in the medical field. Unfortunately, to this day, no generally accepted, evidence-based treatment guidelines or specific management recommendations for MA exist and there has been little progress to ease the burden for patients and improve their quality of life. Thus, the availability of catumaxomab as a specific tumor-directed therapy is a clear benefit for patients in this difficult situation. Catumaxomab reduces the need for punctures, improves quality of life, and even seems to improve life expectancy in a number of cases."

"I have been significantly involved in the development of catumaxomab as an intraperitoneal treatment for ovarian cancer and its withdrawal from the market, driven solely by commercial factors, was a regrettable decision, especially considering the potential benefits for patients. Based on my extensive experience with the drug, both in clinical work and research, I am convinced that this treatment is a key element in controlling the very dramatic symptoms of this disease while providing the best supportive care possible", **added Prof. Jalid Sehouli, MD, director of the Clinic Campus Virchow and Campus Benjamin Franklin Charité Center Gynecology, Charité – Universitätsmedizin Berlin.** "The observed safety profile is very favorable, especially compared to currently available treatments. Catumaxomab has the potential to become the backbone of therapeutic protocols for patients with malignant ascites and I look forward to integrating the treatment in my clinical routine."

In addition to MA, the use of catumaxomab in other indications and additional routes of administration are currently being investigated to further exploit its therapeutic potential in EpCAM-positive carcinomas. A Phase I dose escalation and expansion study (CATUNIBLA) has already completed recruitment in high and intermediate-risk non-muscle invasive bladder cancer (HR-NMIBC), representing a market opportunity for catumaxomab of 1.35bn € in 2030 [DelveInsight, Non-Muscle Invasive Bladder Cancer (NMIBC) – Market Insight, Epidemiology and Market Forecast – 2030]. Encouraging interim data from the trial regarding safety and efficacy were recently presented at the ESMO 2024 conference in Barcelona (Link).

KORJUNY® – the re-approval of the first bispecific trifunctional antibody approved for cancer

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). A pioneering treatment, catumaxomab was the first T cell engager trifunctional antibody and the first drug in the world approved specifically for the

treatment of MA and has since proven its safety and anti-tumor efficacy in more than 2000 patients.

While catumaxomab was voluntarily withdrawn from the EU markets in 2017 due to commercial reasons, its first approval sparked a worldwide growing interest in the development of bispecific T-cell engagers for cancer treatment.

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 a tumor associated antigen highly expressed on almost all carcinomas (as e.g. gastric-, colorectal-, ovarian-, prostate-, pancreas-, bladder-, lung- and endometrial cancer) and is also known as a marker on tumor initiating cancer stem cells – a main driver of metastasis. Therefore, it is a promising approach for targeted treatment of various carcinomas.

About LINDIS Biotech GmbH

LINDIS Biotech GmbH, a biopharmaceutical company with a proprietary multi-specific antibody platform and an advanced development pipeline, was founded in 2010 by Dr. Horst Lindhofer, a pioneer in the area of immune -oncology and inventor of the Triomab® platform. LINDIS Biotech's Triomab® platform stands out in the multi-specific antibody market due to its unique ability to engage three instead of just two different cell types making LINDIS the only company that owns a technology which combines extremely effective tumor cell destruction with a patient-specific vaccination effect.

Lindis, which is holding the IP of the Triomab® – trifunctional antibody -platform, decided to re-develop catumaxomab after acquisition of all necessary rights.

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