PRESS RELEASE – FOR TRADE AND BUSINESS MEDIA ONLY

LINDIS BIOTECH AND PHARMANOVIA ANNOUNCE EUROPEAN MARKETING AUTHORISATION APPROVAL FOR CATUMAXOMAB, A FIRST-IN-CLASS TREATMENT FOR MALIGNANT ASCITES

- CATUMAXOMAB BECOMES THE ONLY APPROVED DRUG THERAPY FOR MALIGNANT ASCITES, A RARE AND DEBILITATING COMPLICATION OF ADVANCED-STAGE CANCER
- UNDER A LICENSING AGREEMENT, LINDIS HAS GRANTED PHARMANOVIA THE EXCLUSIVE RIGHTS TO BRING CATUMAXOMAB TO MARKET AND TO LEAD ALL ACTIVITIES TO LAUNCH CATUMAXOMAB ACROSS EUROPE
- THIS MARKS ANOTHER MILESTONE FOR PHARMANOVIA, AS IT DEEPENS ITS FOOTPRINT WITHIN SPECIALTY PHARMACEUTICALS

MUNICH, GERMANY, AND BASILDON, UK, 13 February 2025

LINDIS Biotech GmbH, a clinical stage biopharmaceutical company with a proprietary multi-specific antibody platform and an advanced development pipeline in immuno-oncology, and Pharmanovia, a global pharmaceutical company that commercialises novel medicines and revitalises, extends and expands the lifecycle of established medicines, today announced that catumaxomab has received marketing authorisation from the European Commission (EC), making the drug the only approved drug therapy for malignant ascites (MA) for patients living with this debilitating condition across Europe.

Under a licensing agreement, LINDIS has granted Pharmanovia the exclusive rights to bring catumaxomab to market and spearhead its launch across Europe.
Catumaxomab, a first-in-class therapeutic, is specifically designed to treat malignant ascites in adults with certain types of cancer (epithelial cellular adhesion molecule (EpCAM)-positive carcinomas) who are not eligible for other systemic anticancer therapies.[i] Malignant ascites is a serious complication of advanced-stage cancers, characterised by the buildup of fluid in the abdomen, causing significant discomfort and severely impacting quality of life. The condition leads to considerable symptoms such as abdominal distension, pain, shortness of breath, fatigue, and fever.[ii]

Stephen Deacon, Chief Scientific Officer at Pharmanovia commented; "This European Commission approval of catumaxomab is a significant milestone for people living with malignant ascites.

Catumaxomab represents a novel therapeutic approach to this challenging condition. By targeting tumour cells and harnessing the power of the patient's own immune system, we aim to improve quality of life for those living with malignant ascites in Europe."

Pharmanovia CEO, Dr. James Burt, highlighted the broader implications of the approval; "This approval not only brings a much-needed treatment to people with malignant ascites but also exemplifies Pharmanovia's commitment to deepening our footprint within the specialty pharmaceutical sector. We are dedicated to delivering innovative and improved medicines to people in need, and this approval reinforces our position as a leader in providing access to essential therapies."

Dr. Horst Lindhofer, Chief Executive Officer of Lindis Biotech, added: "We are delighted to receive marketing approval for catumaxomab. The approval highlights its potential to address the significant medical and treatment challenges faced by patients with malignant ascites. These individuals often endure invasive procedures like paracentesis, which carry risks of complications and severely impact their quality of life. Partnering with Pharmanovia to support commercialization, we are committed to ensuring that this groundbreaking therapy becomes accessible to all patients who can benefit from it."

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Notes to editors

About Pharmanovia
Pharmanovia is a global lifecycle management healthcare company. Our purpose is to make medicines fit for tomorrow, to improve the lives of patients globally.

We do this by rediscovering, repurposing or re-engineering established medicines or by bringing to market novel medicines to improve patient outcomes and experiences.

With a diverse and growing team in over 160 countries across the globe, we deliver high-quality solutions, ethically and sustainably, across our four core therapeutic areas – Endocrinology, Neurology, Cardiovascular and Oncology both in rare and established diseases or conditions.

Lindis Biotech
Lindis Biotech is a clinical stage bio-pharmaceutical company that is committed to the development of Triomab® antibodies – a new class of T-cell engaging

bispecific trifunctional antibodies, empowering the immune system to turn malignant cancers into manageable and possibly curable diseases.

About CATUMAXOMAB

Catumaxomab was originally granted marketing authorisation under the brand name Removab in the EU on 20 April 2009 for treatment of malignant ascites in adults with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible. The product has not been marketed since 2014 and on 2 June 2017 the product was withdrawn from the EU due to commercial reasons.

On 17th October Lindis Biotech GmbH received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) with the brand name KORJUNY®.

Catumaxomab effectively destroys cancer cells by attaching to two antigens: EpCAM and CD3 to form a bridge between the cancer cells and the T-cells. This brings the cells close together so that the T-cells can kill the cancer cells. Catumaxomab also attaches and activates Fc-gamma receptor positive immune cells like e.g. monocytes and macrophages, which also helps the body's immune system to not only attack and destroy cancer cells, but also potentially induce a vaccination effect.[iii,iv]

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.

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[iii]https://www.ema.europa.eu/en/documents/overview/removab-epar-summary-public_en.pdf

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