Aleta Biotherapeutics Receives Innovation Passport Designation for Biologic CAR T-Cell Therapy Engager ALETA-001

Designation Intends to Accelerate Regulatory Review Process and Facilitate U.K. Patient Access to Medicines for Seriously Debilitating and Life-Threatening Diseases

ALETA-001 Was Developed to Address the Urgent Unmet Need of Patient Relapse After CD19-Targeted CAR T-Cell Cancer Treatment

NATICK, Mass., November 7, 2022 – Aleta Biotherapeutics (Aleta), a privately held immuno-oncology company with novel biologic CAR T engagers that work in synergy with cell therapies to improve outcomes for patients, announces that the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) has granted an Innovation Passport under the Innovative Licensing and Access Pathway (ILAP) for Chimeric Antigen Receptor (CAR) T-cell therapy Engager candidate ALETA-001 for the treatment of patients suffering from the B-cell malignancies, non-Hodgkin lymphoma a (NHL) and Acute Lymphoblastic Leukemia (ALL), and who have failed to respond or have relapsed post-CD19 CAR T-cell therapy. ALETA-001 is expected to enter clinical development in 2023 with Cancer Research UK's Centre for Drug Development sponsoring and conducting a Phase 1/2a clinical trial.

The Innovation Passport is the first step in the ILAP process, triggering the MHRA and its partner agencies, including The All Wales Therapeutics and Toxicology Centre (AWTTC), National Institute for Health and Care Excellence (NICE), and the Scottish Medicines Consortium (SMC), to chart a roadmap for regulatory and development milestones to enable faster patient access to medicines in the U.K. To receive an Innovation Passport, a medicine must address conditions that are life-threatening or seriously debilitating, and there must be an existing significant patient or public health need.

"This designation for our biologic CAR T-cell therapy engager ALETA-001 marks an important step in addressing the high unmet need for patients who relapse or progress following CD19-targeted CAR T-cell therapy for blood cancers, such as lymphoma and leukemia," stated Paul Rennert, Co-Founder, Acting Chief Executive Officer and Chief Scientific Officer, Aleta Biotherapeutics. "In collaboration with our partner Cancer Research UK, we are excited to move ALETA-001 forward to potentially transform the lives of patients living with blood cancers," continued Rennert.

Dr. Nigel Blackburn, Cancer Research UK's Director of Drug Development, stated, "We are so pleased to receive this designation for ALETA-001, which reboots CAR T-cell therapy by bridging a patient's circulating CD19-targeted CAR T-cells to cancer cells expressing CD20.

While CAR T-cell therapy has revolutionized hard-to-treat blood cancer outcomes, a majority of patients will see their cancer return, and this is where the critical potential of ALETA-001 exists. ALETA-001 is a promising approach to address this significant treatment gap for patients who currently lack effective options."

In June 2021, Aleta Biotherapeutics and Cancer Research UK announced a collaboration in which Cancer Research UK's Centre for Drug Development will fund, sponsor, and conduct the first-in-human Phase 1/2a clinical trial of ALETA-001, which will be led by Dr. Sridhar Chaganti's Cellular and CAR T-cell therapies team at the Queen Elizabeth Hospital and University Hospitals Birmingham NHS Foundation Trust, Birmingham UK. In the Cancer Research UK-sponsored trial, patients with B-cell lymphoma/leukemia who have received CD19-targeted CAR-T cell therapy but did not achieve a complete response or who relapsed from a complete response will be enrolled. Aleta retains all rights to further develop and commercialize ALETA-001.

About Biologic CAR T-Cell Therapy Engager (CTE) ALETA-001
ALETA-001 is an off-the-shelf preclinical biologic program developed to treat and prevent cell therapy relapse of existing CD19-targeted CAR T-cell therapies, termed CAR19 T cells. ALETA-001 bridges CAR19 T cells to a second antigen, CD20. ALETA-001 binds to B-cell lymphomas and leukemias expressing CD20 antigens and restores tumor expression to CD19. 'Recoating' CD20-expressing cancer cells to express CD19 addresses the critical issues of tumor CD19 antigen loss and density and holds the potential to restore potent killing in patients who are no longer responding to previously administered, circulating CD19-targeted CAR T-cell therapy due to reduction or loss of tumor CD19 expression. In June 2021, Aleta and Cancer Research UK announced a collaboration in which Cancer Research UK will fund, sponsor, and conduct the Phase 1/2a clinical trial of ALETA-001.

About Aleta Biotherapeutics
Aleta Biotherapeutics is an immune-oncology company with a portfolio and platform of novel off-the-shelf biologic CAR T engagers (CTEs) that work in synergy with cell therapies to improve outcomes for patients. Aleta's CTEs bridge CAR T-cell therapies to target multiple tumor antigens, binding to existing tumor antigens and changing the tumor antigen expression to match the CAR T receptor. Aleta's CTEs address the critical issues of tumor antigen loss, density and heterogeneity, which optimizes the potential for potent killing by separately administered cell therapies, including existing CAR19 T-cell therapies.

ALETA-001 and ALETA-005 are designed to treat and prevent cell therapy relapse of circulating CAR19 and B-cell maturation antigen (BCMA) T-cell therapies by restoring tumor antigen expression to match CAR T receptors. ALETA-004 is Aleta's first CTE program to bind CTEs to multiple tumor antigens and fundamentally change tumor cell antigen expression, thereby bridging the tumors to match a specific CAR T-cell therapy. In the case of ALETA-004, Aleta's CTE changes the expression of Acute Myeloid Leukemia (AML), a non-B cell tumor, to express CD19, which allows the potential for CAR CD19 cell therapies to treat AML. http://www.aletabio.com/

About Cancer Research UK's Centre for Drug Development
Cancer Research UK has an impressive record of developing novel treatments for cancer. The Cancer Research UK Centre for Drug Development has been pioneering the development of new cancer treatments for 25 years, taking over 140 potential new anti-cancer agents into clinical trials in patients. It currently has a portfolio of 21 new anti-cancer agents in preclinical development, Phase I or early Phase II clinical trials. Six of these new agents have made it to market including temozolomide for brain cancer, abiraterone for prostate cancer and rucaparib for ovarian cancer. Two other drugs are in late development Phase III trials. www.cruk.org.uk/cdd

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