Aleta Biotherapeutics and Cancer Research UK collaborate to advance blood cancer therapy into the clinic

NATICK, Mass., June 23, 2021 – Aleta Biotherapeutics ('Aleta') and Cancer Research UK today announced a collaboration to advance the early phase clinical development of Aleta's CAR-T cell engager candidate, ALETA-001.

Aleta is a privately held immuno-oncology company focused on transforming cellular therapeutics to allow a broad spectrum of cancer indications to be targeted, and Cancer Research UK is the world's leading cancer charity dedicated to saving lives.

Under the terms of the clinical development partnership, 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 Amit Patel's Cellular and CAR-T therapies team at The Christie NHS Foundation Trust in Manchester, UK.

ALETA-001 has been developed to benefit people with B-cell lymphoma and leukemia whose disease has progressed after receiving CD19 CAR-T cell therapy, and it is hoped that ALETA-001 will offer a new therapy for these patients who have limited treatment options.

CAR-T cell therapy works by targeting the T cell response against cancer through the engineering of T cells to recognize CD19 proteins on the surface of lymphoma and leukemia cells*. CAR-T cell therapy is showing promising results in treating people with blood cancers who are no longer responding to current lines of treatment.

However, over half of the patients treated with CD19 CAR-T cell therapy relapse, mostly due to reduction or loss of CD19 expression. Through binding CD20 present on the surface of cancer cells, ALETA-001 reactivates the CD19 CAR-T cells by effectively 'recoating' the cancer cell with the target CD19 proteins** and restoring the CAR-T cells ability to recognise and engage the cancer cell.

In the Cancer Research UK-sponsored Phase 1/2a trial, patients with B-cell lymphoma/leukemia who have received CD19 CAR-T cell therapy but did not achieve a complete response or who relapsed from a complete response will be enrolled. After the recommended Phase 2 dose of ALETA-001 has been determined, Aleta will initiate a multi-center, single arm, pivotal Phase 2 trial in the United States focused on diffuse large B-cell lymphoma (DLBCL) patients. This clinical trial will be designed to support potential accelerated approval of ALETA-001.

Aleta retain the rights to further develop and commercialize ALETA-001 and will receive a licence to the results of the clinical trial from Cancer Research UK in return for undisclosed success-based milestone and royalty payments.

Paul Rennert, President, Co-Founder and Chief Scientific Officer, Aleta Biotherapeutics, said: "We are deeply honored to be partnering with Cancer Research UK to rapidly advance our lead drug candidate, ALETA-001, into the clinic. There is an urgent need to develop new therapies that can help people with B-cell cancers, such as lymphoma and leukemia, whose cancer has progressed after treatment with CD19 CAR-T cell therapy. Our collaboration with Cancer Research UK is a strong endorsement of the potential of our scientific platform to address the critical issues of CAR-T cell persistence, tumour antigen loss leading to patient relapse, and tumour antigen heterogeneity. We look forward to working with Cancer Research UK's exceptional network of experienced clinical trial investigators and researchers to conduct the trial."

Nigel Blackburn, Cancer Research UK's Director of Drug Development, said: "CAR-T cell therapy has been transformative in treating patients with hard-to-treat blood cancers, but many will see their cancer return and treatment options begin to run out. ALETA-001 uses a simple yet elegant method to redirect a patient's circulating CD19 CAR-T cells against cancer cells expressing CD20, and we hope this could be a new treatment avenue for blood cancer. This is a landmark collaboration for Cancer Research UK as it's the first-in-human trial for a new drug that reboots CAR-T cell therapy, and we look forward to progress its early clinical development with Aleta."

Notes to editor

***** CAR T cell therapy consists of T cells that have been taken from a patient and are reprogrammed in the lab to recognize cancer cells so they can target and kill them more effectively. T cells are taken from a patient and are engineered in the lab to carry a specific CD19 receptor on their surface, which will allow them to target and kill the cancer cells through binding the CD19 antigen present on B cell leukemia and lymphoma cells. The CAR-T cells are then given back to the patient to mount an immune response directed at cancer cells. CAR-T therapy is thus a patient specific personalized anti-cancer treatment.

** In order to replace and increase CD19 antigen expression on the cancer cell surface, ALETA-001 binds to CD20 on the tumour cell leading to the presentation of the CD19 extracellular domain which is recognised and engaged by circulating CD19 CAR-T cells leading to cancer cell killing. CD20 is another type of receptor found expressed on cancer cells, but it appears to be more stable than CD19 and its expression is rarely lost.

About Aleta Biotherapeutics

Aleta Biotherapeutics is an immuno-oncology company focused on transforming cellular therapeutics to allow a broad spectrum of cancer indications to be targeted, including currently intractable solid tumors. The company was founded by Paul Rennert and Roy Lobb, who bring extensive scientific and leadership experience in immunology, oncology, and drug development to this new enterprise. Aleta has created a unique portfolio of multi-antigen targeting solutions for cell therapy, designed to address the critical issues of CAR-T persistence, tumor antigen loss leading to patient relapse, and tumor antigen heterogeneity. 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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