



Arcellx Announces FDA Clearance of IND Application for ACLX-001, a Controllable Cell Therapy Utilizing the Company's ARC-SparX Platform, for the Treatment of Multiple Myeloma

Phase 1 Clinical Trial Expected to Begin in the Second Half of 2021

GAITHERSBURG, Md., April 6, 2021 (GLOBE NEWSWIRE) – – Arcellx, a privately held clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for ACLX-001, an engineered cell

therapy for the treatment of multiple myeloma. ACLX-001 is the first clinical application of the company's ARC-SparX platform of controllable and adaptable cell therapies. The study builds on the company's first Phase I trial of CART-ddBCMA, which demonstrated the advantages of the company's proprietary binding domains as a basis for its platform of classical single infusion CAR-T's as well as its controllable and adaptable ARC-SparX CAR-T's. The company plans to initiate the Phase 1 clinical trial for ACLX-001 in the second half of 2021.

The IND for ACLX-001 for the treatment of multiple myeloma follows the readout of the clinical results for the first six patients treated with CART-ddBCMA at the 2020 American Society of Hematology meeting. The data presented showed all six multiple myeloma patients responded per IMWG criteria, with four of those patients achieving stringent complete response. The therapy was also well-tolerated, and CAR-T related toxicities resolved rapidly.

"Building on our Phase I clinical trial where we demonstrated the clinical significance of our novel binding domain in patients suffering from refractory multiple myeloma, ACLX-001 is the next step in validating our differentiated platform," said Rami Elghandour, Chairman and Chief Executive Officer of Arcellx. "Demonstrating a safe and effective cell therapy that is controllable and adaptable has the potential to be transformative for the field of cell and gene therapy. We're excited about the broad clinical

applications this will enable including our programs in acute myelogenous leukemia (AML) and solid tumors.”

ARC-SparX therapies consist of synthetic off-the-shelf SparX proteins which bind the intended antigen and signal autologous engineered immune cells, ARC-T cells, to destroy the tumor target. ARC-T cells cannot recognize the tumor without SparX proteins and can only destroy a diseased cell when attached to a SparX-antigen complex. By adjusting the dose and frequency of SparX administration, the activity of the ARC-T cells can be managed and controlled. Additionally, treatment with alternate SparX proteins can redirect ARC-T cells to different disease antigens to potentially address relapsed and refractory disease due to tumor heterogeneity or antigen escape. Arcellx is developing a collection of antigen-specific SparX proteins to treat a range of cancer and autoimmune diseases in the community setting.

About Arcellx, Inc.

Arcellx is a clinical-stage biopharmaceutical company developing adaptive and controllable cell therapies for the treatment of patients with cancer and autoimmune diseases. The Arcellx vision is to utilize our novel proprietary platform to bring superior cell therapies to more patients through the care of academic and community practices worldwide. More information can be found at www.arcellx.com.

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