

Arcellx Announces Dosing of First Patient in its Phase 1 Clinical Trial Evaluating ACLX-001, the First Therapeutic in the Dosable and Controllable ARC-SparX Platform, for the treatment of Patients with Relapsed or Refractory Multiple Myeloma

-- ARC-SparX is a novel CAR-T cell therapy treatment designed to allow for controllability and adaptability to potentially reduce toxicities associated with serious dose-limiting adverse events and overcome tumor heterogeneity --

-- Initial data anticipated in 2023 --

FOSTER CITY, Calif., May 10, 2022 /PRNewswire/ -- Arcellx, Inc. (NASDAQ: ACLX), a biotechnology company reimagining cell therapy through the development of innovative immunotherapies for patients with cancer and other incurable diseases, today announced that the first patient has been dosed in its open-label, multicenter ACLX-001 Phase 1 clinical trial (NCT04155749) to evaluate the company's novel ARC-SparX program in patients with relapsed or refractory multiple myeloma (r/r MM). ARC-SparX is a universal cell therapy platform comprised of SparX (soluble protein antigen-receptor X-linkers) proteins engineered to target BCMA on myeloma cells together with ARC-T (Antigen Receptor Complex-T) cells that are dosed separately and are engineered to activate only when engaged with a SparX protein bound to a myeloma cell. Both the ARC-T cells and SparX proteins utilize the company's proprietary novel synthetic binding scaffold called the D-Domain.



"Our ARC-SparX platform, powered by our proprietary D-Domain technology, has the potential to yield transformative therapies that can unleash the full potential of CAR-Ts to treat challenging conditions, including solid tumors. By

addressing antigen heterogeneity and dose limiting toxicities, ARC-SparX could help many patients and address significant unmet clinical needs," said Rami Elghandour, [Arcellx's chairman and chief executive officer](#). "ACLX-001 is intended to demonstrate the advantages for our ARC-SparX platform technology and may potentially enable rapid development of future ARC-SparX programs in our portfolio. We look forward to enrolling additional patients in this study and evaluating the clinical outcomes."

"We are excited to be participating in this clinical trial to evaluate ACLX-001 in patients with relapsed or refractory multiple myeloma," said Binod Dhakal, M.D., M.S., associate professor of medicine, Division of Hematology/Oncology, Medical College of Wisconsin, and clinical investigator on both Phase 1 trials of CART-ddBCMA and ACLX-001. "ARC-SparX provides physicians with the ability to control the dose and frequency of SparX administration. This may allow the physician to better manage toxicities associated with traditional CAR-T therapies, potentially increasing patient access to this treatment option."

Initial data from the ACLX-001 Phase 1 study is expected in 2023. For more information about the clinical trial program, visit [ClinicalTrials.gov](#) (NCT04155749).

About the ARC-SparX Platform Technology

The ARC-SparX platform is designed to allow for controllability and adaptability to potentially reduce toxicities that are often associated with serious dose-limiting adverse events and to overcome tumor heterogeneity. It is a modular therapy which utilizes a universal ARC-T cell combined with an off-the-shelf SparX protein to separate the tumor-recognition and tumor-killing functions. SparX (soluble protein antigen-receptor X-linkers) proteins utilize our D-Domain technology engineered to recognize antigens on the surface of diseased cells and flags those cells for detection by the ARC-T cells. ARC-T cells express a D-Domain-based CAR engineered to specifically recognize a unique TAG in the SparX protein. ARC-T cells are dosed separately and only activated to kill the target cell when they encounter a SparX protein bound to the target antigen and thus are controlled through SparX dose modulation. Arcellx has developed a collection of SparX proteins that bind different antigens on the surface of diseased cells. Multiple SparX proteins

with different antigen specificity can be administered to potentially address antigen heterogeneity or antigen escape that contribute to relapsed and refractory disease.

About the Phase 1 Study Evaluating ACLX-001 for Patients with Relapsed or Refractory Multiple Myeloma (NCT04155749)

The Phase 1 study evaluating ACLX-001 in adults with relapsed or refractory multiple myeloma (r/r MM) is a first-in-human, open-label, multicenter, dose escalation clinical trial designed to evaluate ARC-SparX, in which a matrix escalation of either ARC-T cells or SparX-001 or both may be escalated based on clinical correlative data, including pharmacokinetics of SparX-001 and ARC-T expansion. The primary objective of this study is to evaluate the safety and tolerability of ARC-SparX. A secondary objective is to identify a dosing strategy associated with ARC-T cell expansion kinetics that results in the best mix of efficacy, as determined by International Myeloma Working Group response criteria, and safety profile.

About Arcellx, Inc.

Arcellx, Inc. is a clinical-stage biotechnology company reimagining cell therapy by engineering innovative immunotherapies for patients with cancer and other incurable diseases. Arcellx believes that cell therapies are one of the forward pillars of medicine and Arcellx's mission is to advance humanity by developing cell therapies that are safer, more effective, and more broadly accessible. Arcellx's lead product candidate, CART-ddBCMA, is being developed for the treatment of relapsed or refractory multiple myeloma (r/r MM) in an ongoing Phase 1 study. CART-ddBCMA has been granted Fast Track, Orphan Drug, and Regenerative Medicine Advanced Therapy designations by the U.S. Food and Drug Administration.

Arcellx is also advancing its dosable and controllable CAR-T therapy, ARC-SparX, through two programs: a Phase 1 study of ACLX-001 for r/r MM, initiated in the second quarter of 2022; and ACLX-002 in relapsed or refractory acute myeloid leukemia and high-risk myelodysplastic syndrome, expected to enter the clinic in the second half of 2022.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements in this press release that are not purely historical are forward-looking statements, including Arcellx's expectations regarding the timing of clinical trials and results for its product candidates. The forward-looking statements contained herein are based upon Arcellx's current expectations and involve assumptions that may never materialize or may prove to be incorrect. These forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, including those set forth in Part I, Item 1A (Risk Factors) of Arcellx's Annual Report on Form 10-K and in other reports, including Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, that Arcellx may file from time to time with the Securities and Exchange Commission. These forward-looking statements are made as of the date of this press release, and Arcellx assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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