



Arcellx to Present Data from Phase 1 Study of CART-ddBCMA Demonstrating Continued Positive Response in Patients with Relapsed and Refractory Multiple Myeloma at the 2021 ASCO Annual Meeting

100% (12/12) overall response rate per IMWG criteria observed across all dose levels

GAITHERSBURG, Md., May 19, 2021 (GLOBE NEWSWIRE) – Arcellx, a privately held clinical-stage biopharmaceutical company, today announced the release of updated clinical data from the first 12 evaluable patients treated in the ongoing Phase 1 study of CART-ddBCMA for the treatment of patients with relapsed and refractory multiple myeloma. CART-ddBCMA is the company's autologous, BCMA-specific CAR-modified T-cell therapy utilizing a novel synthetic binding domain. The clinical results will be presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting on June 4, 2021.

[CART-ddBCMA Clinical Results](#)

All patients enrolled in the study have poor prognostic factors with 10 of 12 patients penta-refractory and all 12 patients having had at least three prior treatments.

As of the data cutoff on April 14, 2021,

- 12 of 12 patients achieved responses per IMWG criteria (median follow-up of 197 days; (Min – Max) 29-449 days)
 - 5 patients achieved stringent complete responses (sCR)
 - 1 patient achieved a complete response (CR)
 - 3 patients achieved very good partial responses (VGPR)
 - 3 patients achieved partial responses (PR)
- One patient achieved VGPR despite prior progression on BCMA-targeted therapy
- Responses in 11 patients are ongoing, with evidence that responses deepen over time

“CART-ddBCMA continues to induce deep and durable responses in a heavily pretreated patient population with poor prognostic factors, including five patients who have no signs of disease following a single infusion of CART-ddBCMA CAR-T cells,” commented Matthew J. Frigault, M.D., study investigator and Assistant Director of the Cellular Therapy Service at Mass General Cancer Center and Instructor at Harvard Medical School. “These updated clinical results indicate that CART-ddBCMA’s synthetic BCMA binding domain contributes to a therapeutic benefit. The next steps are to enroll additional patients and gather long-term data to affirm these early results.”

Six of the 12 patients were treated at the first dose level of 100 million CAR+ T cells and six were treated at the second dose level of 300 million CAR+ T cells. Similar efficacy was observed at both dose levels at comparable time points. Consistent with previous results, the therapy was generally well-tolerated, and CAR-T-related toxicities were manageable and resolved at both dose levels. In the 300 million arm, one patient experienced Grade 3 CRS and one patient experienced Grade 3 ICANS, and no patients in the 100 million arm experienced Grade 3 CRS or Grade 3 ICANS.

Based on the responses observed in the first six patients, including four patients who have achieved and maintained sCR beyond day 300 post-treatment, new patients enrolled in the Phase 1 study will be treated at the lower dose.

About CART-ddBCMA

CART-ddBCMA is Arcellx's BCMA-specific CAR-modified T-cell therapy utilizing the company's novel BCMA-targeting binding domain for the treatment of patients with relapsed and refractory multiple myeloma that is currently in a Phase 1 study. Arcellx's proprietary binding domains are novel synthetic proteins engineered for reduced immunogenicity and designed to bind specific therapeutic targets. CART-ddBCMA has been granted Fast Track Designation and Orphan Drug Designation by the U.S. Food and Drug Administration. Additional information about the trial can be found at

<https://www.clinicaltrials.gov/ct2/show/NCT04155749>.

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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