

Arcellx Announces Publication in Blood Advances of Clinical Results from the Dose Escalation Cohorts of its CART-ddBCMA Phase 1 Study in Patients with Relapsed or Refractory Multiple Myeloma

100% ORR; 75% CR/sCR; and evidence of durable clinical benefit in a population with poor prognostic features observed in the dose escalation cohorts with CART-ddBCMA

FOSTER CITY, Calif. , May 9, 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 the publication of clinical data from its dose escalation cohorts in its ongoing Phase 1 study of CART-ddBCMA for the treatment of patients with relapsed or refractory multiple myeloma (r/r MM). The data were published in *Blood Advances*, the open-access journal of the American Society of Hematology.



The publication entitled, "*Phase 1 Study of CART-ddBCMA for the treatment of subjects with relapsed and refractory multiple myeloma*," reported the following:

- Twelve patients in the dose escalation cohorts received a single dose of either 100×10^6 CART-ddBCMA (DL1, n=6) or 300×10^6 CART-ddBCMA (DL2, n=6) following a standard lymphodepletion regimen.
- No cases of Grade 3 or higher CRS or ICANS occurred at DL1, the recommended Phase 2 dose.
- No Parkinsonian-like movement disorders or atypical neurological toxicities were observed.
- The maximally tolerated dose was not reached.
- All patients dosed responded to CART-ddBCMA (ORR 100%) and 9/12 (75%) patients achieved CR/sCR.
- Responses deepened over time and at the data cut (November 4, 2021; median follow-up 56 weeks), 7/9 (78%) of evaluable patients achieved minimal residual disease negativity at 10^{-5} or greater.
- These findings demonstrate the potential safety of CART-ddBCMA cells and durable responses to CART-ddBCMA in r/r MM patients.

The full online publication can be accessed [here](#).

"We are honored to have the clinical results of the first 12 patients treated in the dose escalation cohorts with CART-ddBCMA published in a prominent hematologic journal," said Rami Elghandour, [Arcellx's chairman and chief executive officer](#). "Given these initial results, we expanded our Phase 1 study at our intended Phase 2 pivotal study dose of 100 million cells, and believe these data are indicative of the potential for CART-ddBCMA to be a best-in-class treatment option for patients with multiple myeloma. We look forward to presenting new clinical data at ASCO on June 5 and initiating our Phase 2 pivotal study for CART-ddBCMA in the second half of this year."

About Multiple Myeloma

Multiple Myeloma (MM) is a type of hematological cancer in which diseased plasma cells proliferate and accumulate in the bone marrow, crowding out healthy blood cells and causing bone lesions, loss of bone density, and bone fractures. These abnormal plasma cells also produce excessive quantities of an abnormal immunoglobulin fragment, called a myeloma protein (M protein), causing kidney damage and impairing the patient's immune function. Multiple myeloma is the third most common hematological malignancy in the United States and Europe, representing approximately 10% of all hematological cancer cases and 20% of deaths due to hematological malignancies. The median age of patients at diagnosis is 69 years with one-third of patients diagnosed at an age of at least 75 years. Because MM tends to afflict patients at an advanced stage of life, patients often have multiple co-morbidities and toxicities that can quickly escalate and become life-endangering.

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 or refractory multiple myeloma. CART-ddBCMA is currently in a Phase 1 study. Arcellx's proprietary binding domains are novel synthetic proteins designed to bind specific therapeutic targets. CART-ddBCMA has been granted Fast Track, Orphan Drug, and Regenerative Medicine Advanced Therapy Designations by the U.S. Food and Drug Administration.

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, into the clinic through two programs: ACLX-001 in r/r MM and ACLX-002 in relapsed or refractory acute myeloid leukemia and high-risk myelodysplastic syndrome. Visit www.arcellx.com for more information.

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 timing of the clinical trials for its product candidates and the reporting of results thereof and the potential beneficial characteristics, safety, tolerability, efficacy and therapeutic effects of 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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