Arcellx Announces New Positive Data for Its iMMagine-1 Study in Patients with Relapsed and/or Refractory Multiple Myeloma

-- Anito-cel demonstrated 96% ORR and 74% CR/sCR at a median follow-up of 15.9 months; responses continue to deepen over time --

-- Overall MRD negativity was 95% and sustained MRD negativity for ≥6 months was 83%, both at 10^{-5} sensitivity level --

-- 12-month PFS and OS rates were 82.1% and 94.0%; 18-month PFS and OS rates were 67.4% and 88.0%; 24-month PFS and OS rates were 61.7% and 83.0% --

-- To date, no delayed or non-ICANS neurotoxicities, including no Parkinsonism, no cranial nerve palsies, no Guillain-Barré syndrome, and no immune effector cell-associated enterocolitis have been observed with anito-cel to date; all patients were dosed at least 12 months ago --

-- The company reiterates its planned 2026 commercial launch --

-- iMMagine-1 data to be presented during an oral presentation at the ASH Annual Meeting on Saturday, December 6, 2025 --

-- Company to host a live webcast event with an expert panel of clinicians during ASH --

REDWOOD CITY, Calif. – December 6, 2025 – 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 new positive data from its pivotal Phase 2 iMMagine-1 study of anitocabtagene autoleucel (anito-cel), in patients with relapsed or refractory multiple myeloma (RRMM). These data are being presented during an oral presentation at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition on Saturday, December 6, 2025 at 2:45 p.m. ET. Anito-cel is partnered with Kite, a Gilead Company.

October 7, 2025, is the data cutoff date for this presentation and the BLA submission. These data are for all 117 patients with a median follow-up of 15.9 months. All patients received a single infusion of anito-cel (target dose of 115×10^6 CAR+ viable T cells). Within the study population, 102 of 117 patients (87%) were triple refractory, 48 of 117 patients (41%) were penta refractory, 21 of 117 patients (18%) had extramedullary disease, and 47 of 117 patients (40%) had high risk cytogenetics. Patients received a median of three prior lines of therapy, with 65 of 117 patients (56%) having received three prior lines.

Overall response rate (ORR) was 96% (112/117) with a complete response/stringent complete response (CR/sCR) rate of 74% (86/117) and a very good partial response or higher (≥VGPR) rate of 88% (103/117), per Independent Review Committee (IRC) assessment. Of those evaluable for minimal residual disease (MRD) testing at the time of this data cut, 95% (91/96) achieved overall MRD negativity. Of the MRD evaluable group with sufficient follow up, 83% (54/65) sustained MRD negativity for ≥6 months, at a minimum of 10^{-5} sensitivity. Six-month progression-free survival (PFS) and overall survival (OS) rates were 93.1% and 95.7%, respectively; 12-month PFS and OS rates were 82.1% and 94.0%, respectively; 18-month PFS and OS rates were 67.4% and 88.0% respectively, and 24-month PFS and OS rates were 61.7% and 83.0% respectively. Median PFS and median OS have not been reached.

To date, no delayed or non-ICANS neurotoxicities, including no Parkinsonism, no cranial nerve palsies, no Guillain-Barré syndrome, and no immune effector cell-associated enterocolitis have been observed with anito-cel with all patients dosed more than 12 months ago.

Conclusions

Preliminary results from the Phase 2 iMMagine-1 study continue to demonstrate deep and durable responses with a predictable and manageable safety profile in a fourth-line or higher (4L+) RRMM population, including triple- and penta-refractory disease. Notably, no delayed or non-ICANS neurotoxicities, including no Parkinsonism, no cranial nerve palsies, no Guillain-Barré syndrome, and no immune effector cell-associated enterocolitis have been observed with anito-cel to date.

“These data are compelling and are an important advancement for patients living with multiple myeloma,” said Dr. Krina Patel, Associate Professor, Department of Lymphoma/Myeloma, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, and iMMagine-1 and iMMagine-3 clinical investigator. “I am encouraged by the depth of responses in the iMMagine-1 study. For clinicians, we rely on therapies that deliver continued meaningful efficacy, a predictable safety profile, and reliable manufacturing. Anito-cel demonstrates that it could become a significant new treatment option in our efforts to improve outcomes for patients with multiple myeloma.”

Rami Elghandour, Arcellx’s Chairman and Chief Executive Officer, said, “The data from iMMagine-1 continue to reinforce our belief that anito-cel is poised to become a category leader in treating multiple myeloma patients. Our plans for a 2026 commercial launch are well underway. We are building a world-class commercial and medical affairs organization to ensure broad patient access and physician support. We remain committed to a launch of unparalleled scale and impact to meet the needs of the myeloma community and to demonstrate the true potential of cell therapy. We could not have reached this transformational moment without the collaboration of the physicians and patients who participated in the iMMagine-1 study, our team members who go above and beyond the status quo every day, and our partners at Kite. We believe we can set a new standard for what’s possible with a CAR T treatment option for multiple myeloma. We have come so far together, and the best is yet to come as we sit on the precipice of helping so many more patients in need.”

ASH Presentation Details

Title: Phase 2 registrational study of anitocabtagene autoleucel for the treatment of patients with relapsed and/or refractory multiple myeloma: Updated results from iMMagine-1

Speaker: Krina K. Patel, MD, MSc, MD Anderson Cancer Center
Session Name: 655. Multiple Myeloma: Cellular Therapies: Clinical Trial Advances in CAR T-Cell Therapy for Multiple Myeloma
Session Date: Saturday, December 6, 2025
Session Time: 2:00 p.m. – 3:30 p.m. ET
Presentation Time: 2:45 p.m. ET
Location: OCCC – West Hall E1
Publication Number: 256
Submission ID: abs25-4541

Webcast Event:

Arcellx will host a live webcast event with a panel of clinician experts to discuss the iMMagine-1 clinical results on Saturday, December 6, 2025 at 8:00 p.m. ET. The event will be accessible from Arcellx's website at www.arcellx.com in the Investors section. A replay of the webcast will be archived and available for 30 days following the event.

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. MM 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 Anitocabtagene Autoleucel (anito-cel)

Anitocabtagene autoleucel (anito-cel, previously CART-ddBCMA) is the first BCMA-directed CAR T-cell therapy to be investigated in multiple myeloma that utilizes Arcellx's novel and compact binder known as the D-Domain. The small, stable D-Domain binder enables high CAR expression without tonic signaling and is designed to quickly release from the BCMA target. This combination may allow for the effective elimination of multiple myeloma cells without severe immunotoxicity. Anito-cel has been granted Fast Track, Orphan Drug, and Regenerative Medicine Advanced Therapy Designations by the U.S. Food and Drug Administration.

About Arcellx and Kite Collaboration

Arcellx and Kite, a Gilead Company, formed a global strategic collaboration and license agreement to co-develop and co-commercialize anito-cel for patients with multiple myeloma. Anito-cel is currently being developed in a Phase 2 registrational pivotal study and a global Phase 3 randomized controlled study for relapsed and/or refractory multiple myeloma (RRMM). Kite and Arcellx will jointly commercialize the anito-cel asset in the United States, and Kite will commercialize the product outside the United States.

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. For more information on Arcellx, please visit www.arcellx.com. Follow Arcellx on X @arcellx and LinkedIn.

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, but not limited to, statements regarding anito-cel pharmacology profile, tolerability and toxicity trends; the anticipated timing of updated iMMagine-1 data; the expectation of anito-cel to be a significant or differentiated CAR-T treatment option for RRMM; scale and quality of Arcellx's commercial and medical affairs organization; the anticipated commercial launch of anito-cel in 2026, subject to FDA approval, in partnership with Kite; the expectation of ensuring broad patient access and physician support and commitment to launching anito-cel with unparalleled scale and impact to meet physician expectations; and the potential impact of Arcellx's product candidates and platforms on patients and cell therapy. 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 II, Item 1A (Risk Factors) in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, filed with the Securities and Exchange Commission (SEC) on November 5, 2025, and the other documents 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.

Investor Contact:
Myesha Lacy
Arcellx, Inc.
ir@arcellx.com
510-418-2412

Media Contact:
Andrea Cohen
Sam Brown LLC
andreacohen@sambrown.com
917-209-7163

###