



NEWS RELEASE

Artiva Biotherapeutics Announces Positive Initial Safety and Translational Data Supporting Deep B-Cell Depletion with AlloNK® in Autoimmune Disease

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32 patients with autoimmune disease treated with AlloNK plus anti-CD20 monoclonal antibody (mAb) as of October 1, 2025, data cutoff

All patients received AlloNK as outpatients, and the majority were treated in community rheumatology trial sites with no specialized oncology oversight, demonstrating the feasibility of administering this regimen outside the hospital setting

No cytokine release syndrome (CRS), or immune effector cell-associated neurotoxicity syndrome (ICANS)

Consistent and complete B-cell depletion was observed in all patients with autoimmune disease treated with AlloNK + mAb by Day 13 of treatment, consistent with the experience for AlloNK + mAb in B-cell driven lymphoma

Artiva remains on track to share initial clinical response data and conduct U.S. Food and Drug Administration (FDA) regulatory interactions to align on pivotal trial design for AlloNK in refractory rheumatoid arthritis (RA) in the first half of 2026

Management will host a webcast today at 8:00 a.m. ET

SAN DIEGO, Nov. 12, 2025 (GLOBE NEWSWIRE) -- **Artiva Biotherapeutics, Inc.** (Nasdaq: ARTV) (Artiva), a clinical-

stage biotechnology company whose mission is to develop effective, safe, and accessible cell therapies for patients with devastating autoimmune diseases and cancers, today announced positive initial safety and translational data from ongoing clinical trials of AlloNK® (also known as AB-101) in combination with rituximab or obinutuzumab for the treatment of autoimmune disease. The findings highlight that AlloNK, an allogeneic, non-genetically modified, cryopreserved, off-the-shelf natural killer (NK) cell therapy, was generally well tolerated and demonstrated deep B-cell depletion in outpatient and community settings.

“AlloNK + mAb aims to capture the optimal balance of cell therapy efficacy with the tolerability and convenience of biologics for patients and physicians. Our treatment regimen has the potential to drive deep B-cell depletion with a high rate of durable responses, with a tolerability profile highly compatible with community administration, based on this initial data,” said Fred Aslan, M.D., President and Chief Executive Officer of Artiva Biotherapeutics. “We believe the deep B-cell depletion field has the potential to impact every indication in autoimmune disease, and Artiva is leading with RA, the autoimmune disease with the largest number of patients refractory to standard of care. We believe AlloNK could be the first agent in the deep B-cell depleting field to potentially start a global pivotal trial in refractory RA following our planned interactions with FDA in the first half of 2026.”

“It is remarkable to see such consistent B-cell depletion, particularly using a high-sensitivity assay, and favorable safety and tolerability in this first clinical data readout of AlloNK in autoimmune disease,” said Subhashis Banerjee, M.D., Chief Medical Officer of Artiva Biotherapeutics. “The AlloNK treatment regimen, which includes Cy / Flu, has been generally well tolerated in autoimmune patients. There were no CRS or ICANS events and a low infection rate reported. We believe this supports administration in outpatient and community rheumatology settings.”

AlloNK is currently being explored in three ongoing Phase 1 and 2 clinical trials for the treatment of refractory RA, Sjögren’s disease (SjD), idiopathic inflammatory myopathies, systemic sclerosis (SSc), and systemic lupus erythematosus (SLE)/lupus nephritis (LN). All patients receive a standard conditioning regimen of cyclophosphamide (Cy) and fludarabine (Flu) prior to treatment with AlloNK (three weekly doses) and anti-CD20 monoclonal antibody, either rituximab or obinutuzumab, in an outpatient setting.

Key Data Highlights

Initial safety and tolerability profile in the community setting

- As of the data cutoff date of October 1, 2025, 32 patients have been treated with AlloNK plus anti-CD20 monoclonal antibody therapy across refractory RA, SjD, SLE, LN, and SSc in two company-sponsored trials and an investigator-initiated basket trial
- Patients received either 1 billion or 4 billion AlloNK cells per dose
- All patients were treated as outpatients, and the majority were treated at community rheumatology trial sites,

with no specialized oncology oversight demonstrating feasibility of AlloNK administration and patient management in the community setting

- The treatment regimen was generally well tolerated. Most treatment-emergent adverse events (TEAEs) were Grade 1 or 2, transient, and consistent with expected effects of Cy and Flu conditioning
- No AlloNK-related Grade 3+ TEAEs or serious adverse events were reported
- No discontinuations were reported
- No CRS, ICANS, Graft-versus-Host Disease or hypogammaglobulinemia were reported
- Among patients with three months of follow-up, no new safety signals were identified
- Only one patient hospitalized for an adverse event, a skin infection unrelated to AlloNK, in the 28-day window post treatment
- Data as of the cutoff date suggest that overall patient and physician experience and emerging tolerability profile are consistent with the treatment journey typically observed with intravenous mAb therapies

Initial translational data

- As of the data cutoff date of October 1, 2025, all 23 patients with samples analyzed demonstrated non-quantifiable peripheral CD19+ B-cell levels by Day 13 of treatment, irrespective of baseline B-cell counts
 - Similarly, results from a high-sensitivity B-cell depletion assay with 10- to 50-fold higher sensitivity than typical assays demonstrated non-quantifiable peripheral CD19+ B-cell levels, further supporting the intended mechanism of action for AlloNK
- B-cell reconstitutions in the four patients treated with AlloNK + rituximab who had achieved B-cell reconstitution as of the data cutoff demonstrated predominantly naïve and transitional cells at the time of reconstitution, in line with what has been observed with CD19-auto-CAR-T treatment
- The depth and consistency of B-cell depletion are comparable to those achieved with CD19-auto-CAR-T cell therapies and meaningfully greater than rituximab alone as reported in published studies

Opportunity and Unmet Need in Refractory RA

- Significant unmet need for patients who have failed at least two biologic or targeted synthetic disease modifying anti-rheumatic drugs (b/ts DMARDs) representing more than 150,000 patients in the U.S.
- Meaningful room for improvement in ACR50 response in patients who have failed at least two b/ts DMARDs:
 - Real-world registry for approved agents shows 10 – 20% ACR50 response in patients who have failed two or more b/ts DMARDs

Upcoming Milestones

- Artiva on track to share initial clinical response data across dose levels from more than 15 refractory RA

patients, several of whom will have 6 months or more follow up, in 1H 2026

- Artiva plans to conduct FDA regulatory interactions in 1H 2026 to align on the pivotal trial design for AlloNK in refractory RA

Webcast Details

Artiva management will host a webcast today at 8:00 a.m. E.T. to discuss the initial safety and translational data for AlloNK in combination with anti-CD20 mAbs across autoimmune diseases and unmet need and opportunity in refractory RA. Investors and the general public are invited to listen to the webcast. A live question and answer session will follow the formal presentation. To register for the event, please click [here](#).

A webcast replay will be made available through the "Investors" section on Artivabio.com.

About Artiva Biotherapeutics

Artiva is a clinical-stage biotechnology company whose mission is to develop effective, safe and accessible cell therapies for patients with devastating autoimmune diseases and cancers. Artiva's lead program, AlloNK[®] (also known as AB-101), is an allogeneic, off-the-shelf, non-genetically modified, cryopreserved NK cell therapy candidate designed to enhance the antibody-dependent cellular cytotoxicity effect of monoclonal antibodies to drive B-cell depletion. AlloNK is currently being evaluated in three ongoing clinical trials for the treatment of B-cell driven autoimmune diseases, including a company-sponsored basket trial across autoimmune diseases that includes rheumatoid arthritis and Sjögren's disease and an investigator-initiated basket trial in B-cell driven autoimmune diseases. Artiva's pipeline also includes CAR-NK candidates targeting both solid and hematologic cancers. Artiva was founded in 2019 as a spin out of GC Cell, formerly GC Lab Cell Corporation, a leading healthcare company in the Republic of Korea, pursuant to a strategic partnership granting Artiva exclusive worldwide rights (excluding Asia, Australia and New Zealand) to GC Cell's NK cell manufacturing technology and programs.

Artiva is headquartered in San Diego, California. For more information, please visit www.artivabio.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this press release that are not statements of historical fact are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding: expectations of Artiva Biotherapeutics, Inc. (the "Company") regarding the potential of AlloNK and the treatment regimen with AlloNK, anti-CD20 antibodies, and Cy/Flu conditioning, including potential benefits, safety and tolerability profile, design, goals, mechanism of action, activity, accessibility, efficacy, expected effects, scalability, convenience, feasibility of administration outside the hospital setting or in outpatient and community rheumatology settings,

integration into routine autoimmune disease care, treatment journey, potential to drive a high rate of durable responses, and applicability to other autoimmune disease indications; plans to share clinical response data in refractory RA, including the scope and timing of such data; plans to conduct FDA regulatory interactions, including the timing and outcome of such interactions; the potential to start a global pivotal trial in refractory RA and to be the first agent in the deep B-cell depleting field to do so; the unmet need and opportunity in refractory RA; the Company's planned webcast; and the Company's mission. These forward-looking statements are based on the beliefs of the management of the Company as well as assumptions made by and information currently available to the Company. Such statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks and uncertainties. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. These and other factors that may cause the Company's actual results to differ from current expectations are discussed in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the section titled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this press release is given. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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