NEWS RELEASE

Artiva Announces Positive Initial Clinical Data with AlloNK® Across Multiple Autoimmune Diseases and FDA Alignment to Initiate Phase 3 Registrational Trial in Rheumatoid Arthritis in 2026

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Initial clinical data demonstrated 71% ACR50 response in refractory rheumatoid arthritis (RA) patients with at least six months of follow-up in the company-sponsored Phase 2a basket trial, with no patients relapsing or requiring new immunomodulatory agents

AlloNK treatment regimen demonstrated tolerability results supportive of outpatient administration in community rheumatology settings, with no CRS, ICANS, or treatment discontinuations observed in autoimmune patients treated with AlloNK

More than 70 autoimmune patients treated with AlloNK across more than 40 active clinical sites, mostly in community settings, providing a strong foundation for planned registrational trial initiation in H2 2026

U.S. Food and Drug Administration (FDA) alignment on a single registrational randomized controlled trial evaluating AlloNK plus rituximab versus rituximab alone in approximately 150 refractory RA patients, with ACR50 at six months as the primary endpoint

Multiple oral and poster presentations at EULAR 2026, including a late-breaking oral presentation on AlloNK clinical efficacy in refractory RA, Sjögren disease (SjD) and systemic sclerosis (SSc)

SAN DIEGO, May 08, 2026 (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 debilitating autoimmune diseases, today announced positive initial clinical data from ongoing clinical trials evaluating AlloNK® (also known as AB-101) in combination with rituximab. As of the April 3, 2026 data cutoff, the initial clinical dataset includes 21 refractory RA patients with at least 12 weeks of follow-up, including 13 patients with six months of follow-up, from Artiva's company-sponsored Phase 2a basket trial and an investigator-initiated basket trial evaluating AlloNK in B-cell driven autoimmune diseases. The broader autoimmune dataset also includes 11 SjD patients and five SSc patients, including seven SjD patients and four SSc patients with at least six months of follow-up.

Artiva also announced alignment with the FDA on a single registrational randomized controlled trial design for AlloNK in refractory RA expected to enroll approximately 150 RA patients who have had an inadequate response to two or more biologic or targeted synthetic disease modifying anti-rheumatic drugs (b/tsDMARDs) of distinct classes. Patients are expected to be randomized 2:1 to receive AlloNK plus rituximab or rituximab alone, with ACR50 response at six months as the primary efficacy endpoint.

"A new chapter begins for Artiva as we advance the first deep B-cell depleting therapy into a registrational trial in RA and share clinical data demonstrating AlloNK's potential to drive auto-CAR-T-like activity across indications through an off-the-shelf, more scalable and cost-effective therapeutic approach that could address refractory patients in the community setting," said Fred Aslan, M.D., president and chief executive officer of Artiva Biotherapeutics. "I am very proud of the Artiva team. In less than four years since the seminal deep B-cell depletion work was published by Schett et al., we rapidly initiated and supported trials in autoimmune diseases, activated more than 40 sites globally, treated more than 70 autoimmune patients and built a robust clinical trial network, mostly in the community setting, to support our efforts to conduct an efficient randomized controlled trial in RA, one of the largest refractory autoimmune patient populations."

"After reviewing AlloNK's initial clinical data in refractory RA, I am encouraged by the magnitude and consistency of improvements across multiple measures of disease activity, including swollen and tender joint counts, CDAI, DAS28 and ACR responses," said Stanley Cohen, M.D., adjunct professor of internal medicine at University of Texas Southwestern Medical School and program director of rheumatology at THR Presbyterian Dallas. "Patients who have had an inadequate response to multiple distinct b/tsDMARDs remain difficult to treat, and there is a significant need for new therapeutic approaches that can deliver meaningful clinical benefit. I am pleased to be advising Artiva on their planned Phase 3 registrational trial of AlloNK in refractory RA."

"Since the inception of Artiva's clinical trials in autoimmune diseases, I have treated more than 20 patients with AlloNK in my community practice and have observed meaningful improvements in many refractory patients across

indications," said Guillermo J. Valenzuela, M.D., F.A.C.R., medical director of Integral Rheumatology & Immunology Specialists (IRIS). "Importantly, these clinical responses have been observed alongside a favorable tolerability profile that supports administration and management in the community setting. I am enthusiastic to see AlloNK advance into a Phase 3 trial for refractory RA."

As of April 30, 2026, more than 70 autoimmune patients had initiated treatment with AlloNK across ongoing clinical trials, with more than 40 clinical sites activated globally. All patients have been treated in the outpatient setting, with the majority treated in community rheumatology clinics, providing a strong foundation to support Artiva's planned Phase 3 registrational trial in refractory RA.

Key Data Highlights

Initial clinical activity observed in refractory RA patients

- As of the April 3, 2026 data cutoff, pooled data included 21 refractory RA patients with at least 12 weeks of follow-up, including 13 patients with six months of follow-up, from Artiva's company-sponsored Phase 2a basket trial and an investigator-initiated basket trial.
- Patients had longstanding and highly active disease, with mean disease duration of 14.8 years. All patients had high disease activity at baseline and 81% had failed two or more prior b/tsDMARD classes.
- Five of seven patients (71%) with six months of follow-up in the company-sponsored Phase 2a basket trial achieved an ACR50 response. In the investigator-initiated basket trial, five of six patients (83%) with six months of follow-up demonstrated greater than 50% improvement on at least four of five measured components; HAQ-DI and Pain scores were not collected in the IIT, and therefore ACR50 could not be adequately assessed. Patients with only 12 weeks of follow-up demonstrated early improvements across disease activity measures consistent with those observed in patients with six or more months of follow-up. As of the data cutoff, no patients started a new b/tsDMARD following treatment with AlloNK plus rituximab.
- Nineteen of 21 patients demonstrated clinically meaningful reductions from baseline in both CDAI (defined as reductions of at least 12 points) and DAS28-ESR (defined as reductions of at least 1.2 points). Clinically meaningful reductions in CDAI and DAS28-ESR were observed by three months and deepened at six months, with mean reductions from baseline at six months of 37 points in CDAI and 2.8 points in DAS28-ESR.

Tolerability profile of AlloNK plus rituximab continues to support outpatient administration in community rheumatology settings

- All patients have been treated in the outpatient setting, with the majority treated in community rheumatology clinics.

- No cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) was reported.
- No treatment discontinuations due to adverse events and no serious adverse events related to AlloNK were reported.
- The most common treatment-emergent adverse events were consistent with those associated with rituximab or cyclophosphamide/fludarabine conditioning. The Grade 3 or higher infection rate was 2% (n=1), which is comparable to serious infection rates reported for approved RA therapies, including rituximab and other biologic or targeted therapies.
- During the initial 28-day post-treatment period, no patients were hospitalized for infection. Two of 55 autoimmune patients treated with AlloNK plus rituximab were hospitalized for treatment-emergent adverse events during this period: one admission for dehydration in a SjD patient with diarrhea and one admission for diabetic ketoacidosis in a RA patient with insulin-dependent Type 2 diabetes. Neither hospitalization was deemed related to AlloNK.

Deep B-cell depletion and B-cell reconstitution profile support proposed mechanism of action

- Uniform and consistent B-cell depletion in peripheral blood was observed by Day 13 in all 51 patients treated with cyclophosphamide/fludarabine, AlloNK and rituximab who had available samples as of the April 3, 2026 data cutoff.
- Complete B-cell depletion was observed using a high-sensitivity assay in all 28 RA patients evaluated as of the data cutoff.
- B-cell reconstitution in all patients treated with AlloNK plus rituximab demonstrated a predominance of naïve/transitional B cells, consistent with the hypothesized B-cell “reset” mechanism.

Initial clinical responses in Sjögren disease and systemic sclerosis support broader potential across B-cell-driven autoimmune diseases

- As of the April 3, 2026 data cutoff, initial clinical data included 11 patients with moderate-to-severe SjD and five patients with moderate-to-severe SSc. Clinical responses observed in these patient populations were consistent with the RA data and support the potential of AlloNK across B-cell driven autoimmune diseases.
- In SjD, patients demonstrated mean improvements at six months (n=7) of 8.6 points in ClinESSDAI, 6.6 points in ESSDAI and 3.0 points in ESSPRI, with a mean increase of 0.76 mL/min in stimulated salivary flow. All patients were off steroids as of the April 3, 2026 data cutoff.
- In SSc, patients demonstrated a mean improvement in mRSS of 9.5 points at six months (n=4), with 100% achieving rCRISS25 and 50% achieving rCRISS50 responses among patients with six months of follow-up. No

patients were on steroids as of the April 3, 2026 data cutoff.

FDA Alignment and Registrational Strategy in Refractory RA

Following a recent FDA interaction, Artiva plans to initiate a Phase 3 randomized controlled trial evaluating AlloNK in approximately 150 RA patients who have had an inadequate response to two or more b/tsDMARDs of distinct classes. Artiva has alignment with the FDA on its plans to conduct a single registrational trial. Patients are expected to be randomized 2:1 to receive AlloNK plus rituximab or rituximab alone, with ACR50 response at six months as the primary efficacy endpoint. Rituximab was selected as the active comparator because it is a component of the proposed AlloNK treatment regimen, is approved for the treatment of RA and has demonstrated ACR50 responses at six months in line with other approved RA therapies. Patients randomized to the rituximab-alone control arm who do not respond are expected to have the opportunity to cross over to the AlloNK plus rituximab arm at six months.

The proposed AlloNK dosing regimen is expected to include two doses of 4 billion AlloNK cells administered on Days 6 and 20 together with rituximab, following conditioning with low-dose cyclophosphamide and fludarabine on Days 1, 2 and 3.

Assuming a favorable risk-benefit profile, Artiva believes its ongoing and planned autoimmune clinical trials, including the planned Phase 3 registrational trial in refractory RA, will generate a safety database of more than 250 patients treated with AlloNK plus rituximab, consisting primarily of RA patients and including patients with other autoimmune diseases, to support a potential biologics license application (BLA) submission for RA. Based on FDA feedback, Artiva believes pooled safety data across multiple autoimmune indications may supplement RA-specific safety data.

Subject to final protocol and regulatory considerations, the trial is expected to be conducted globally across more than 80 sites, including approximately 40 sites already active in Artiva's ongoing autoimmune clinical program. Artiva expects to initiate the registrational trial in the second half of 2026 and report primary efficacy data in the second half of 2028, with a potential BLA submission in 2029.

Significant opportunity and unmet need in refractory RA

RA remains a large and underserved autoimmune disease, particularly among patients who have had an inadequate response to two or more b/tsDMARD classes, also known as difficult-to-treat RA under EULAR guidelines. Artiva estimates that between 150,000 to 200,000 patients in the U.S. have failed two or more b/tsDMARDs, representing approximately 25% of the U.S. b/tsDMARD-treated RA population. Real-world registry analyses and published data suggest that patients in this setting only have an 11% to 19% likelihood of achieving an ACR50 response with currently available therapies.

Artiva's objective is to develop AlloNK as a deep B-cell depleting therapy in combination with rituximab with the potential to deliver ACR50 responses in at least 50% of refractory RA patients at six months, provide durable clinical benefit and offer an outpatient treatment profile that can be administered and managed in community rheumatology settings. Artiva expects patients in the rituximab-alone control arm to achieve ACR50 responses of approximately 20% to 25% at six months.

Multiple abstracts accepted for presentation at **EULAR 2026**

- Late Breaking Oral Abstract Presentation - LB0003: AB-101, an Outpatient-Administered Allogeneic NK Cell Therapy Combined with Rituximab, Generates Robust Clinical Efficacy Responses Comparable with Autologous CAR T in 31 Patients with Rheumatologic Diseases
- Oral Abstract Presentation - OP0129: AB-101, an Allogeneic NK Cell Therapy, Combined with Rituximab was Highly Effective in Severe Sjögren Disease: Experience in First Patient Treated
- Poster View Presentation - POS1177: Robust and Durable Clinical Responses Observed Following Treatment with AB-101, an Allogeneic NK Cell Therapy, Combined with Rituximab in Patients with Severe Rheumatoid Arthritis and Inadequate Response to Multiple Prior Targeted Therapies
- Poster Tour - POS0355: AB-101, an Allogeneic NK Cell Therapy, in Combination with Anti-CD20 Monoclonal Antibodies, Consistently Achieves Deep B-cell Depletion Comparable with CAR T Cell Therapies in Patients with Rheumatologic Diseases

About AlloNK®

AlloNK® (also known as AB-101) is an allogeneic, off-the-shelf, non-genetically modified, cryopreserved natural killer (NK) cell therapy candidate designed to enhance the antibody-dependent cellular cytotoxicity effect of monoclonal antibodies to drive B-cell depletion. In rheumatoid arthritis (RA) and other autoimmune diseases, AlloNK is being evaluated in combination with anti-CD20 monoclonal antibodies following a standard conditioning regimen of low-dose cyclophosphamide and fludarabine. AlloNK is currently being evaluated across multiple ongoing clinical trials in B-cell driven autoimmune diseases, including refractory RA, Sjögren disease, systemic sclerosis and idiopathic inflammatory myopathies (myositis).

About Artiva Biotherapeutics

Artiva is a clinical-stage biotechnology company whose mission is to develop effective, safe and accessible cell therapies for patients with debilitating autoimmune diseases. 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 disease and an investigator-initiated basket trial in B-cell driven autoimmune diseases. Artiva plans to initiate a Phase 3 registrational trial evaluating AlloNK in refractory RA in 2026. 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 regarding the potential benefits, accessibility, effectiveness and safety of AlloNK, including based on interim pooled data across clinical trials; Artiva's registrational strategy, including trial design, plans to conduct a single registrational Phase 3 trial for AlloNK and generate sufficient trial and pooled safety data to support a BLA submission, and Artiva's expectations on timing and FDA alignment with such strategy; Artiva's expectations on the timing to initiate and report data for the Phase 3 trial; Artiva's expectations with respect to ACR50 responses in the Phase 3 trial for both AlloNK and the control arm; estimates regarding the size of patient populations and response rates to existing therapies; and the potential market opportunity for AlloNK. These forward-looking statements are based on the beliefs of the management of Artiva as well as assumptions made by and information currently available Artiva. Such statements reflect the current views of Artiva with respect to future events and are subject to known and unknown risks and uncertainties, including, without limitation, risks inherent in developing product candidates; Artiva's ability to obtain adequate financing to fund its planned clinical trials and other expenses; risks that future clinical trial results may not be consistent with interim, initial, preliminary, or topline results or results from prior preclinical studies or clinical trials; the risk that Artiva's registrational strategy is based in part on its views following its recent meeting with the FDA and later feedback from the FDA may be inconsistent with such meeting or its views from such meeting, including the risk that the official FDA minutes which Artiva expects to receive in the coming weeks may include interpretations, requests for additional data, or conclusions that differ from Artiva's understanding of prior discussions; the risk that differences exist between trial designs, patient characteristics and other factors for the Artiva-sponsored Phase 2a basket trial and an investigator-initiated basket trial, and caution should be exercised in drawing any conclusions from such data across separate trials as such pooling and comparative data is inherently limited and such data may not be directly comparable; and risks related to the legal and regulatory framework for the industry. 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 Artiva's actual results to differ from current expectations are described in further detail under the section

titled “Risk Factors” contained in Artiva’s filings with the Securities and Exchange Commission (the “SEC”), including Artiva’s Annual Report on Form 10-K for the year ended December 31, 2025, and its subsequent Quarterly Reports on Form 10-Q, each as filed or to be filed with the SEC. 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, Artiva 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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