



NEWS RELEASE

Artiva Biotherapeutics Provides Update on Planned AlloNK® Data Disclosures and Development Milestones for the Remainder of 2026

2026-09-08

Updated clinical data expected in the second half of 2026 from at least 20 patients with refractory rheumatoid arthritis (RA) treated with AlloNK and rituximab in the ongoing company-sponsored Phase 2a basket trial, each with at least six months of follow-up, including at least 10 patients who would meet key eligibility criteria for the Phase 3 registrational trial in refractory RA

Updated clinical data expected in the second half of 2026 from at least 10 patients with Sjögren disease (SjD) and at least five patients with systemic sclerosis (SSc), each with at least six months of follow-up

Initiating Phase 3 registrational randomized controlled trial evaluating AlloNK® plus rituximab versus rituximab alone in approximately 150 patients with refractory RA, with further updates on site activation and enrollment initiation expected in the second half of 2026

SAN DIEGO, Sept. 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 provided an update on anticipated data disclosures and development milestones for its lead program, AlloNK® (also known as AB-101), through year-end 2026.

"In the second half of 2026, we are initiating our FDA-aligned Phase 3 trial in refractory RA and planning to disclose updated clinical data from patients in our Phase 2a basket trial with RA, Sjögren disease and systemic sclerosis,"

said Fred Aslan, M.D., chief executive officer of Artiva Biotherapeutics. “With FDA RMAT designation and cash runway expected to extend into 2029 – beyond the planned topline readout from our registrational trial – we believe Artiva is well positioned to potentially be the first company to bring a deep B-cell depleting therapy to market in refractory RA.”

Dr. Aslan continued, “Patients with refractory RA continue to face significant unmet need despite treatment with multiple advanced therapies. We previously reported encouraging ACR50 response rates and no cases of cytokine release syndrome, ICANS or treatment discontinuations due to adverse events among patients with refractory RA treated with AlloNK plus rituximab as of April 3, 2026. We believe these findings support a clinical profile that could make deep B-cell depletion practical in community rheumatology practices, where patients with refractory RA routinely receive care.”

Anticipated 2026 Milestones

Disclose updated clinical data in refractory RA

- Artiva expects to disclose updated clinical data from at least 20 patients with refractory RA treated with AlloNK plus rituximab in the ongoing company-sponsored Phase 2a basket trial, each with at least six months of follow-up, including at least 10 patients who would meet key eligibility criteria for the planned Phase 3 registrational trial in refractory RA.

Disclose updated clinical data in additional B-cell-driven autoimmune diseases

- Artiva expects to disclose updated clinical data from at least 10 patients with Sjögren disease and at least five patients with systemic sclerosis, each with at least six months of follow-up.

Initiate Phase 3 registrational trial in refractory RA

- In the second half of 2026, Artiva is initiating a Phase 3 randomized controlled trial evaluating AlloNK plus rituximab versus rituximab alone in approximately 150 patients with refractory RA who have had an inadequate response to at least two distinct classes of biologic or targeted synthetic disease-modifying anti-rheumatic drugs (b/tsDMARDs), with ACR50 response at six months as the primary efficacy endpoint. Artiva has alignment with the FDA on its plans to conduct a single registrational trial. The trial will evaluate whether AlloNK plus rituximab can achieve an ACR50 response rate greater than 50%, versus an expected response rate of approximately 20% with rituximab alone based on published literature and real-world evidence. Artiva expects to provide further updates on site activation and enrollment initiation during the second half of 2026

and to report topline results by the end of 2028.

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 is initiating a Phase 3 registrational trial of its lead program, AlloNK® (also known as AB-101), in refractory rheumatoid arthritis (RA) in the second half of 2026. AlloNK is an allogeneic, off-the-shelf, non-genetically modified, cryopreserved natural killer (NK) cell therapy candidate designed to enhance antibody-dependent cellular cytotoxicity for a range of antibodies, including anti-CD20 antibodies, and drive deep B-cell depletion. Initial clinical data evaluating AlloNK in combination with anti-CD20 antibodies have demonstrated encouraging activity across multiple B-cell-driven autoimmune diseases, together with a tolerability profile supportive of outpatient administration. Artiva is developing AlloNK to drive deep B-cell depletion through a scalable, outpatient-administered treatment regimen compatible with community rheumatology settings. In addition to refractory RA, AlloNK is being evaluated in Sjögren disease, systemic sclerosis and myositis.

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: the potential benefits, accessibility, practicality, effectiveness, safety and tolerability of AlloNK, including based on interim pooled data across clinical trials, and the potential for administration in an outpatient community setting; the registrational Phase 3 trial for AlloNK, including trial design, expectations for response rates, and timing of initiation, future updates on site activation and enrollment, and topline data readout; and Artiva's ability to generate sufficient data to support a BLA submission; clinical data expected to be available and presented in refractory RA, SjD and SSc, and the timing of such data disclosures; the number of patients with data from the basket study who would be expected to meet the key eligibility criteria for the planned Phase 3 trial; Artiva's ability to realize the potential benefits associated with FDA RMAT designation for AlloNK; Artiva's beliefs regarding its competitive position, including its belief that AlloNK may be the first deep or deep B-cell depleting therapy of any modality to reach patients with, and be approved and commercialized in, refractory RA; and Artiva's future results of operations and financial position, including cash runway. These forward-looking statements are based on the beliefs of the management of Artiva as well as assumptions made by and information currently available to 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 and delays relating to initiation of the Phase 3 registrational trial, activation of clinical trial sites, patient enrollment and the availability and timing of disclosure of

data; 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, or with Artiva's expectations; the risk that the number of patients, or the duration of follow-up for such patients, available for presentation differs from current expectations; the risk that differences exist between trial designs, patient characteristics and other factors for the Phase 3 trial, Artiva-sponsored Phase 2a basket trial and 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; the risk that other deep B-cell depleting therapies may advance more rapidly than Artiva currently anticipates, that Artiva's assessment of publicly disclosed competitor development timelines may be incomplete or inaccurate, and that Artiva may not achieve or be the first to achieve regulatory approval or commercialization of a therapy in this category; the risk that Artiva's registrational strategy is based in part on recent interactions with the FDA and later feedback from the FDA may be inconsistent with past interactions; Artiva's ability to obtain adequate financing to fund its planned clinical trials and other expenses; risks inherent in developing product candidates; 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 discussed in Artiva's filings with the Securities and Exchange Commission (the "SEC"), including the section titled "Risk Factors" in Artiva's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026. 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.

Contacts

Investors & Media

Noopur Batsha Liffick, MPH

NBL LifeSci Advisory LLC

ir@artivabio.com

Source: Artiva Biotherapeutics, Inc.

Source: Artiva Biotherapeutics, Inc.