NEWS RELEASE

Artiva Biotherapeutics Announces Refractory Rheumatoid Arthritis as Lead Indication, Upcoming Data Releases, and Corporate Update

2025-10-16

Prioritization of refractory rheumatoid arthritis (RA) as lead indication for AlloNK® development

FDA Fast Track Designation received for AlloNK in refractory RA, representing the first drug candidate in the deep B-cell depleting category to receive this designation with the potential to become the first in the category to advance to a pivotal trial in RA, pending FDA feedback expected in 1H 2026

Continued execution and enrollment progress with more than 20 patients treated with AlloNK + monoclonal antibody (mAb) therapy across company-sponsored and investigator-initiated trials in autoimmune diseases

Upcoming translational data release expected to show uniform, consistent, deep B-cell depletion supporting AlloNK's intended mechanism of action

Upcoming safety data release expected to also highlight favorable tolerability profile observed to date and ease-of-use of the regimen that includes cyclophosphamide/fludarabine conditioning, and feasibility of administration and patient management in outpatient rheumatology clinics

SAN DIEGO, Oct. 16, 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, announced today that the U.S. Food and Drug Administration (FDA)

has granted Fast Track Designation to AlloNK® (also known as AB-101) for the treatment of refractory rheumatoid arthritis (RA) in combination with rituximab and that the Company has prioritized refractory RA as the program's lead indication. AlloNK is believed to represent the first drug candidate in the deep B-cell depleting therapeutic category to receive this designation in refractory RA.

"We are prioritizing refractory RA as our lead autoimmune indication for AlloNK given the size of this underserved population. Despite the many approved therapies in RA, there are over 100,000 patients in the United States who remain treatment refractory and could potentially benefit from a deep B-cell depleting therapy," said Fred Aslan, M.D., Chief Executive Officer of Artiva. "We look forward to sharing the emerging translational and safety data in mid-November, supporting AlloNK's profile as an outpatient-ready therapy capable of achieving deep B-cell depletion, followed by clinical response data in the first half of 2026 from more than 15 refractory RA patients, several of whom will have six or more months of follow-up. In addition, we are planning FDA interactions in the first half of 2026 that could enable AlloNK to become the first deep B-cell depleting therapy to advance to a pivotal trial in patients with RA."

AlloNK's Clinical Opportunity in RA:

RA is a chronic autoimmune disease that affects over 1.5 million people in the United States and can cause painful joint inflammation, progressive joint damage, and disability, if not adequately treated. While existing treatments such as methotrexate, TNF inhibitors, and B-cell depleting antibodies have improved outcomes for many patients, a significant subset becomes refractory and no longer responds to or tolerates these options. These patients face ongoing disease activity, increased risk of disability and joint destruction, and reliance on steroids or immunosuppressants that have long-term toxicity. AlloNK is designed to enhance the activity of B-cell-targeting antibodies, such as rituximab, through antibody-dependent cellular cytotoxicity. This mechanism of action is intended to drive deeper and more durable B-cell depletion than antibodies alone, potentially enabling long-term durable responses.

"I am encouraged by our early data with AlloNK in refractory RA patients. Having contributed to the development of leading RA therapies including Humira® and Orencia®, I have witnessed the unmet need among patients with refractory RA who continue to suffer from inadequate disease control," said Subhashis Banerjee, M.D., Chief Medical Officer of Artiva. "Of note, most patients with RA are treated at community rheumatology clinics rather than at large academic medical centers. Emerging deep B-cell depleting therapies such as CAR-T and T-cell engagers can be limited by the need for hospitalization or specialized oncology oversight, making them challenging for widespread use. With its infusion-ready, off-the-shelf format, and ease of use similar to IV-administered RA drugs, AlloNK in combination with rituximab has the potential to address this unmet need in a scalable and broadly accessible way."

Key Highlights:

- Company is prioritizing refractory RA as its lead indication, reflecting the opportunity to address this unmet need with a potentially impactful therapy that can be administered and managed in the community setting
- Received FDA Fast Track Designation for AlloNK in refractory RA, representing the first known drug candidate in the deep B-cell depleting therapeutic category to receive this designation in RA
- More than 20 patients treated with AlloNK + mAb across refractory RA, Sjögren's disease, systemic lupus erythematosus, lupus nephritis, and systemic sclerosis in company-sponsored trials and an investigator-initiated basket trial, at 1 billion and 4 billion cells per AlloNK dose
- Emerging translational and safety data expected to support AlloNK's profile as an outpatient-ready therapy capable of achieving consistent and deep B-cell depletion
- Depending on our regulatory interactions with the FDA, AlloNK has the potential to become the first therapy within the emerging deep B-cell depletion category, which includes auto-CAR-T and T-cell engagers, to advance to a pivotal trial for patients with refractory RA

Upcoming Milestones:

- Company plans to share initial safety and translational data for over 20 patients treated with AlloNK + mAb across multiple autoimmune diseases in mid-November, including insights into the patient journey from community rheumatology sites
    - Translational data expected to highlight uniform, consistent, deep B-cell depletion
    - Safety data expected to highlight tolerability and ease-of-use of the regimen, including cyclophosphamide/fludarabine conditioning regimen, when administered and managed in community clinics
- Company on track to share clinical response data across dose levels from more than 15 refractory RA patients in 1H 2026
- Company plans to conduct FDA regulatory interactions in 1H 2026 to align on the pivotal trial design for AlloNK in refractory RA

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 benefits, accessibility, scalability, ease of use, effectiveness, safety, mechanism of action, and future development of AlloNK, including AlloNK becoming the first deep B-cell depleting therapy to advance to a pivotal trial in patients with RA; the timing and availability of data from the Company's clinical trials or the basket investigator-initiated basket trial; the clinical opportunity and unmet need in RA; the timing and outcome of regulatory interactions; and the Company's ability to benefit from Fast Track or other regulatory designations. 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 June 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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