



NEWS RELEASE

# Artiva Biotherapeutics Announces First Patient Dosed in Phase 1 Trial of AlloNK® Cell Therapy Candidate in Lupus Nephritis

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- To Artiva's knowledge, this marks the first patient to receive an allogeneic, off-the-shelf NK cell therapy in a U.S. clinical trial for treatment of an autoimmune disease
- Data demonstrated AlloNK drove deep depletion of peripheral B-cells and complete responses in relapsed or refractory B-cell-non-Hodgkin lymphoma (B-NHL) patients in ongoing clinical trial, supporting potential mechanism of action relevant to autoimmune disease
- Artiva is collaborating with Lupus Therapeutics to support development of AlloNK through Lupus Clinical Investigators Network sites

SAN DIEGO, April 17, 2024 — **Artiva Biotherapeutics, Inc.**, a clinical-stage company whose mission is to deliver highly effective, off-the-shelf, allogeneic natural killer (NK) cell-based therapies, announced today that the first patient has been dosed in its Phase 1 trial of AlloNK® (also known as AB-101) in combination with monoclonal antibodies for the treatment of lupus nephritis (LN) (ClinicalTrials.gov Identifier: NCT06265220). AlloNK is a non-genetically modified, allogeneic, cryopreserved NK cell therapy candidate being developed to enhance the activity of B-cell targeting monoclonal antibodies to drive B-cell depletion.

Seminal reports with autologous CAR-T cells have demonstrated that cell therapy can deeply and temporarily deplete B-cells with the potential to reset the immune system and provide complete and long-lasting responses in patients with LN. Artiva has analyzed blood samples from patients treated with AlloNK in combination with rituximab, an anti-CD20 antibody that targets B-cells, in a Phase 1/2 multi-center clinical trial in patients with

relapsed or refractory B-cell-non-Hodgkin lymphoma (B-NHL) (ClinicalTrials.gov Identifier: NCT04673617). In all 29 patients with samples analyzed, as of March 26, 2024, all patients achieved non-quantifiable peripheral B-cell levels by Day 8 (except for one patient who achieved such B-cell depletion by Day 15) following the start of therapy, regardless of B-cell levels at baseline. Artiva believes this data provides support for the B-cell depleting mechanism of action. AlloNK has also demonstrated complete responses in B-NHL patients as measured by imaging of tumor lesions. Because of the common tissues of interest, principally the lymphoid tissues, in B-NHL and autoimmune diseases, Artiva believes data in these B-NHL patients provides supporting evidence for the therapeutic mechanism of action in autoimmune disease.

“We are excited to bring AlloNK to patients with autoimmune disease. To our knowledge, this is the first time a patient has received an allogeneic NK cell therapy candidate in a U.S. clinical trial for treatment of an autoimmune disease. We are encouraged by the activity of AlloNK in our NHL trial, demonstrating AlloNK’s ability to drive B-cell depletion and helping validate the therapy’s potential mechanism of action,” said Fred Aslan, M.D., Chief Executive Officer of Artiva. “Furthermore, our ability to combine AlloNK with CD20, CD19, or CD38 directed monoclonal antibodies gives AlloNK the versatility to target distinct B-cell subpopulations across different autoimmune diseases.”

The multi-center, open label clinical trial will assess the safety and clinical activity of AlloNK in combination with rituximab or obinutuzumab in patients with class III or class IV LN who have relapsed or did not respond to previous standard of care treatment approaches. Patients will receive a treatment composed of lymphodepletion with cyclophosphamide and fludarabine, three-doses of AlloNK, and two doses of monoclonal antibody.

“Lupus nephritis is among the most severe manifestations of systemic lupus erythematosus. Many patients do not respond to standard therapies. Examining new treatments could provide more novel options for this patient demographic,” said Kenneth Kalunian, M.D., Professor of Medicine and Director of the Lupus Center of Excellence at UC San Diego School of Medicine.

Artiva is collaborating with Lupus Therapeutics, the clinical research affiliate of the Lupus Research Alliance, to support the evaluation of AlloNK for LN. Lupus Therapeutics has provided advisory services and clinical operations support for the Artiva early development program through sites of the Lupus Clinical Investigators Network (LuCIN). The Network, overseen by Lupus Therapeutics, is comprised of leading research centers throughout North America with the purpose of accelerating and optimizing lupus clinical trials.

#### About Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is a chronic, potentially severe, autoimmune disease characterized by abnormal B-cell function and autoantibody production resulting in a range of clinical manifestations including end-

organ damage and an increased risk of death. SLE affects an estimated 200,000 patients in the U.S. Lupus nephritis (LN) is the most common end-organ manifestation of SLE, affecting approximately 50% of SLE patients.

#### About AlloNK

AlloNK (also known as AB-101) is a non-genetically modified, allogeneic, cryopreserved NK cell therapy candidate developed to enhance the activity of B-cell targeting monoclonal antibodies to drive B-cell depletion. AlloNK is designed as an off-the-shelf therapy to be administered in combination with monoclonal antibodies and accessible in the community setting. As a non-genetically modified cell therapy manufactured without the use of integrating vectors, we believe AlloNK will not be subject to extensive patient follow-up or the potential for secondary malignancy class warnings associated with approved autologous CAR-T therapies. Using the company's cell therapy manufacturing platform, Artiva can generate thousands of doses of cryopreserved, infusion-ready AlloNK cells from a single umbilical cord blood unit while retaining the high and consistent expression of high affinity CD16 and activating NK receptors. The FDA has granted Fast Track designation to AlloNK in combination with rituximab or obinutuzumab for the treatment of lupus nephritis, and AlloNK in combination with rituximab for the treatment of relapsed/refractory non-Hodgkin lymphoma of B-cell origin (B-NHL).

#### About AlloNK Clinical Trials in Autoimmune Disease and Cancer

In an open-label Phase 1 trial, AlloNK will be administered in combination with rituximab or obinutuzumab for treatment of class III or class IV LN in patients who previously failed treatment (ClinicalTrials.gov Identifier: NCT06265220). AlloNK is also being investigated in two clinical trials in cancer. Artiva is conducting a Phase 1/2 multicenter clinical trial (ClinicalTrials.gov Identifier: NCT04673617) to assess the safety and clinical activity of AlloNK, alone and in combination with rituximab in patients with relapsed or refractory B-NHL. Artiva is also collaborating with Affimed N.V. in a Phase 2, open-label, multi-center, multi-cohort study (NCT05883449, LuminICE-203) testing a combination therapy, comprised of AlloNK and the innate cell engager, AFM13, for the treatment of patients with relapsed/refractory CD30-positive lymphomas.

#### About Artiva Biotherapeutics

Artiva is an immunotherapy company with the ability to produce off-the-shelf, allogeneic NK cell therapies at a massive scale. Artiva's mission is to develop effective, safe, and accessible cell therapies for patients with devastating autoimmune diseases and cancers. Artiva's lead program, AlloNK, is a non-genetically modified, allogeneic, cryopreserved NK cell therapy candidate being developed to enhance the activity of B-cell targeting monoclonal antibodies to drive B-cell depletion. Artiva's pipeline also includes a pipeline of CAR-NK candidates targeting both solid and hematopoietic cancers. **Artiva's cell therapy manufacturing platform** incorporates cell expansion, activation, and engineering technology developed by Artiva's strategic partner, GC Cell Corporation, a

member of the GC family of companies, a leading healthcare company in Korea. Artiva is headquartered in San Diego. For more information, visit [www.artivabio.com](http://www.artivabio.com).

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