NEWS RELEASE

Artiva Biotherapeutics Announces FDA Clearance of IND for AlloNK® Cell Therapy Candidate in Combination with Rituximab in Lupus Nephritis

8/16/2023

- his marks the first IND clearance for an allogeneic, off-the-shelf NK or CAR-T cell therapy candidate in autoimmune disease
- Artiva also announced the formation of an advisory board to provide expertise in advancing innovative cell therapies for lupus and other autoimmune diseases

SAN DIEGO, August 16, 2023 — **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 U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for AlloNK® (also known as AB-101), in combination with rituximab for treatment of systemic lupus erythematosus (SLE) in patients with active lupus nephritis (LN). AlloNK is a non-genetically modified, cord blood-derived, allogeneic, cryopreserved NK cell therapy candidate designed to enhance antibody-dependent cellular cytotoxicity (ADCC). This IND clearance marks the first for an allogeneic, off-the-shelf NK or CAR-T cell therapy in autoimmune disease.

AlloNK is currently being investigated in two cancer clinical trials in combination with antibody or NK-engager biologics. Artiva **presented data** at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrating the therapeutic potential and favorable safety profile of AlloNK in combination with rituximab in patients with relapsed/refractory B-cell non-Hodgkin lymphoma (B-NHL).

"Seminal clinical data has been generated using autologous CAR-T cells suggesting that a deeper B cell depletion

can induce complete and long-lasting responses in patients with lupus nephritis. However, the use of autologous CAR-T cells requires apheresis, likely hospitalization, and the potential for serious side effects," said Fred Aslan, M.D., Chief Executive Officer of Artiva. "AlloNK given in combination with rituximab, an anti-CD20 antibody that targets B-cells, is already driving complete responses in late line B-NHL patients in an ongoing Phase 1 study by enhancing the activity of rituximab. Our hypothesis is that AlloNK plus rituximab also has the potential to drive deep B-cell depletion in LN patients with an off-the-shelf therapy that could be administered and managed in an outpatient setting."

As Artiva broadens the applications of AlloNK into autoimmune disease, the company has assembled an advisory board of experts in SLE and LN:

- Kenneth Kalunian, M.D., is a clinician and Professor of Medicine at UC San Diego, where he directs the Lupus Research and Clinical Center of Excellence. Dr. Kalunian participates in multiple lupus clinical networks, including as a founding member of both the Systemic Lupus Erythematosus International Collaborating Clinics (SLICC) and the Lupus Clinical Investigators Network (LuCIN).
- Jill Buyon, M.D., is a clinician and Professor of Rheumatology and Director of the Division of Rheumatology at New York University (NYU) School of Medicine, and Director of the NYU Lupus Center. Dr. Buyon has published more than 200 papers in peer-reviewed science journals and has been an active member of the Accelerating Medicines Partnership.
- Maureen McMahon, M.D., is a clinician and Professor of Medicine / Rheumatology at UCLA and site director of the UCLA Lupus Clinical Trials Network. Her research and clinical work have focused on identifying new treatments for SLE.
- Brad Rovin, M.D., is a Professor of Medicine and Pathology and Director of the Division of Nephrology at The Ohio State University, Wexner Medical Center. Dr. Rovin studies the immunopathogenesis of glomerular and autoimmune diseases and is heavily involved in clinical trial development and design for investigator-initiated and industry-sponsored trials.

"Although rituximab has been used off-label in the treatment of SLE, rituximab alone has been shown to give incomplete B-cell depletion. The addition of allogeneic NK cells as an ADCC-enhancing therapy could significantly enhance rituximab's ability to drive deeper levels of B-cell depletion," said Dr. Kalunian. "Furthermore, SLE patients may have lower levels of NK cells than healthy subjects, and these cells may be functionally impaired. An effective off-the-shelf cell therapy that can be administered and managed in the community setting could be well received by lupus patients and physicians."

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 160,000-320,000 patients in the U.S. Lupus nephritis (LN) is the most common end-organ manifestation of SLE, affecting approximately 40% of SLE patients, and more than 40% of patients with the most severe LN will develop end-stage renal disease requiring dialysis and transplant within 15 years.

About AlloNK®

AlloNK® (also known as AB-101) is a non-genetically modified, cord blood-derived, allogeneic, cryopreserved, ADCC-enhancing NK cell therapy candidate for use in combination with monoclonal antibodies or innate-cell engagers in the out-patient setting. Artiva is investigating AlloNK® in 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 the anti-CD20 monoclonal antibody, rituximab, in patients with relapsed or refractory B-cell-non-Hodgkin lymphoma (B-NHL). Artiva is also investigating the safety and clinical activity of AlloNK in combination with rituximab in patients with lupus nephritis. In addition, Artiva is 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. Artiva selects cord blood units with the high affinity variant of the CD16 receptor and a KIR-B haplotype for enhanced product activity. Using the company's cell therapy manufacturing platform, Artiva can generate thousands of doses of pure, cryopreserved, infusion-ready NK cells from a single umbilical cord blood unit while retaining the high and consistent expression of CD16 and other activating NK receptors, without the need for engineering. AlloNK is being administered in the outpatient setting over multiple doses and multiple cycles.

About Artiva Biotherapeutics

Artiva's mission is to deliver highly effective, off-the-shelf, allogeneic NK cell-based therapies that are safe and accessible to patients. Artiva has taken a Manufacturing-First approach to create a highly scaled process where one umbilical cord blood unit yields thousands of one-billion cell doses of AlloNK. Artiva's pipeline includes AlloNK®, an ADCC enhancer NK-cell therapy candidate for use in combination with monoclonal antibodies or innate-cell engagers. Artiva's pipeline also includes AB-201, an anti-HER2 CAR-NK cell therapy candidate for the treatment of HER2-overexpressing tumors, such as breast, gastric, and bladder cancers, and for which an IND has been allowed by FDA, and a pipeline of CAR-NK candidates targeting both solid and hematopoietic cancers. Artiva has entered into therapeutic NK cell collaborations with Merck Sharp & Dohme and with Affimed N.V. **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**.

Contacts

Media: Jessica Yingling, Ph.D., Little Dog Communications Inc., **jessica@litldog.com**, +1.858.344.8091

Investors: Nicholas Veomett, Ph.D., Artiva Biotherapeutics, **ir@artivabio.com**