



NEWS RELEASE

Artiva Biotherapeutics Receives FDA Fast Track Designation for AlloNK® in Lupus Nephritis

2/22/2024

SAN DIEGO, February 22, 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Artiva's lead program AlloNK® (also known as AB-101) for the treatment of lupus nephritis (LN) in combination with rituximab or obinutuzumab. Artiva previously received FDA clearance of an Investigational New Drug (IND) application for AlloNK in combination with rituximab in LN, marking the first IND clearance of an allogeneic, off-the-shelf NK cell therapy in autoimmune disease. AlloNK is a non-genetically modified, allogeneic, cryopreserved NK cell therapy candidate that enhances the activity of B-cell-targeting monoclonal antibodies to drive B-cell depletion.

"The FDA Fast Track designation gives us an opportunity to accelerate our efforts to bring our AlloNK cell therapy to autoimmunity patients," said Fred Aslan, M.D., Chief Executive Officer of Artiva. "We are encouraged by clinical data from our Phase 1/2 multicenter clinical trial in non-Hodgkin lymphoma, where we observed that AlloNK in combination with rituximab can drive deep B-cell depletion in patients with late-line B-cell cancers. Our therapy has a mechanism very similar to the B-cell targeted autologous CAR-T therapies, but with the benefits of being an off-the-shelf therapy with a better safety profile, and that we believe will not be subject to the secondary malignancy risk associated with genetically engineered cell therapies."

AlloNK is being investigated in a multi-center, open-label clinical trial to assess the safety and clinical activity of AlloNK in combination with anti-CD20 antibodies in patients with LN who have relapsed or did not respond to previous standard of care treatment approaches (ClinicalTrials.gov Identifier: NCT06265220). In addition, safety and

activity have been established for AlloNK in combination with rituximab in a Phase 1/2 multicenter clinical trial in patients with relapsed or refractory B-cell-non-Hodgkin lymphoma (B-NHL) (ClinicalTrials.gov Identifier: NCT04673617).

About AlloNK®

AlloNK® (also known as AB-101) is an allogeneic NK cell therapy candidate designed to enhance the antibody-dependent cellular cytotoxicity (ADCC) effect of monoclonal antibodies or NK cell engagers. AlloNK is a cryopreserved, off-the-shelf therapy with the potential to be administered in the community setting. As a non-genetically modified cell therapy manufactured without the usage 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 CD16 and activating NK receptors. The FDA has granted Artiva Fast Track designations for the treatment of lupus nephritis with AlloNK in combination with rituximab or obinutuzumab, and for the treatment of relapsed/refractory non-Hodgkin lymphoma of B-cell origin with AlloNK in combination with rituximab.

About Fast Track Designation

Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fulfill an unmet medical need, enabling drugs to potentially reach patients earlier. Clinical programs with Fast Track designation may benefit from early and frequent communication with the FDA throughout the regulatory review process. These clinical programs may also be eligible to apply for Accelerated Approval and Priority Review if relevant criteria are met.

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 an allogenic, non-genetically modified NK cell therapy candidate designed to enhance the antibody-dependent cellular cytotoxicity (ADCC) effect of monoclonal antibodies or NK cell engagers. Artiva's pipeline also includes 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.

Contacts

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

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