



NEWS RELEASE

Artiva Biotherapeutics Announces FDA Allowance of IND to Initiate Clinical Trials of AB-101 in Combination with Rituximab for the Treatment of Advanced B-cell Lymphomas

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- AB-101 is an optimized universal NK cell therapy candidate designed for clinical use with tumor-targeted therapeutics
- First clinical program applying Artiva's proprietary large-scale NK-cell manufacturing process for off-the-shelf cellular therapies

SAN DIEGO, December 7, 2020 — Artiva Biotherapeutics, Inc., an oncology company focused on developing and commercializing primary allogeneic natural killer (NK) cell therapies to treat cancer, announced today U.S. Food and Drug Administration (FDA) allowance of the company's investigational new drug (IND) application for AB-101, an optimized and cryopreserved off-the-shelf NK cell therapy. Artiva plans to conduct a Phase 1/2 clinical trial at up to 20 U.S. cancer centers to assess the safety and clinical activity of AB-101 alone and in combination with the anti-CD20 monoclonal antibody, rituximab, in patients with relapsed or refractory B-cell non-Hodgkin lymphoma (NHL) who have progressed beyond two or more prior lines of therapy.

"Monoclonal antibodies are mainstays of cancer therapy, but many patients have sub-optimal responses, and those who progress have limited options," said Tom Farrell, President and CEO of Artiva. "With AB-101, we intend to leverage our proprietary off-the-shelf NK cell platform to enhance and extend the clinical application of monoclonal antibodies and other cancer targeted therapies that rely on NK cells to mediate their anti-cancer activity."

AB-101 is a cryopreserved NK cell product candidate with high and consistent expression of tumor-engaging receptors including the high-affinity variant of CD16. These NK cell attributes have demonstrated improved outcomes for cancer patients in both the transplant and therapeutic monoclonal antibody settings. Furthermore, in preclinical models, AB-101 demonstrates enhanced antibody-dependent cellular cytotoxicity with a variety of therapeutic antibodies.

“Allogeneic NK cells have been tested in clinical trials for more than a decade. Based on this experience, we expect that AB-101 will be well tolerated. This contrasts with T-cell therapies that are associated with life-threatening cytokine release syndrome, neurotoxicity, and graft-versus-host-disease,” said Jason Litten, MD, Chief Medical Officer of Artiva.

About the Clinical Trial

After receiving standard lymphodepleting chemotherapy, patients will receive eight weekly doses of up to four billion NK cells per AB-101 dose. The primary endpoint is objective response rate, per the 2014 Lugano Criteria. In Phase 2, indolent and aggressive NHL patients will receive AB-101 plus rituximab combination therapy in two parallel Simon two-Stage designed cohorts, each with independent interim analyses for objective clinical response. (ClinicalTrials.gov Identifier: [NCT04673617](#))

About AB-101 NK Cell Therapy

Leveraging a proprietary manufacturing platform that enables expansion and cryopreservation of cord blood-derived NK cells, Artiva is advancing AB-101 as a universal primary NK cell product candidate for use in combination with targeting therapies such as monoclonal antibodies or NK cell engagers. Starting cord blood units are selected for B-KIR haplotype and the homozygous polymorphism of CD16 that confers high affinity binding to antibodies, including monoclonal antibody therapies. Starting cells are isolated then expanded and activated utilizing a proprietary campaign-based manufacturing process in a state-of-the-art GMP facility. AB-101 is delivered as cryopreserved vials of one billion highly active NK cells in an infusion-ready media for thawing and administration on demand at the clinical trial site. The manufacturing process generates thousands of cryovials of AB-101 from a single cord blood unit.

About Artiva Biotherapeutics: Scaling NK Cell Therapy for Cancer

Artiva’s mission is to deliver highly effective cellular immunotherapies that are also safe and immediately accessible to cancer patients. Artiva’s pipeline of universal and targeted NK cell therapies leverages the innate anti-tumor biology and safety features of NK cells. The therapies are optimized for enhanced efficacy through chimeric antigen receptors (CARs) or therapeutic antibody combinations. Artiva’s pipeline is built on a manufacturing platform that

supports large-scale production and cryopreservation of off-the-shelf allogeneic NK cell therapies and proprietary CAR-NK technologies to augment therapeutic activity. Artiva's platform incorporates cell expansion, activation, and engineering technology developed by the company's corporate partner, GC LabCell, a member of the GC family of companies, one of the Republic of Korea's leading biopharmaceutical groups. Artiva is headquartered in San Diego.

Media Contact: Jessica Yingling, Ph.D., [Little Dog Communications](https://www.litldog.com), jessica@litldog.com