
AB-110-001 Phase 1b Trial and Related Activities to Support Clinical Development of AB-110

Grant Award Details

AB-110-001 Phase 1b Trial and Related Activities to Support Clinical Development of AB-110

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-10386

Project Objective: Hematologic and immune reconstitution in patients who have received myeloablation conditioning.

Investigator:

Name:	Edward Kavalerchik
Institution:	Angiocrine Bioscience, Inc.
Type:	PI

Disease Focus: Blood Cancer, Cancer

Human Stem Cell Use: Adult Stem Cell

Cell Line Generation: Adult Stem Cell

Award Value: \$5,000,000

Status: Closed

Progress Reports

Reporting Period: Final Operational Milestone #4

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Grant Application Details

Application Title: AB-110-001 Phase 1b Trial and Related Activities to Support Clinical Development of AB-110

Public Abstract: **Therapeutic Candidate or Device**

AB-110 consists of cord blood derived hematopoietic stem and progenitor cells co-cultured and expanded with E-CEL UVEC cells

Indication

Hematologic and immune reconstitution in patients who have received myeloablation conditioning

Therapeutic Mechanism

Stem and progenitor cells (active ingredient) of AB-110 engraft into the bone marrow of patients, rebuilding a new blood and immune system after appropriate preparation called myeloablation. The E-CEL UVEC cells are thought to aid the engraftment of the stem and progenitor cells into the bone marrow via secretion of angiocrine factors. The remainder of the cord blood cells in AB-110 also aid in the engraftment as well as provide anti-viral and anti-bacterial effects after transplantation.

Unmet Medical Need

Unmet medical need is for a safer, more tolerable and effective stem cell transplantation. AB-110 aims to fulfill this need and provide patients greater access to this potentially curative treatment.

Project Objective

The objective is to complete the Phase 1b trial.

Major Proposed Activities

- Initiation of patient recruitment and submission of Interim Analyses Report of initial cohort to the FDA
- Submission of 180 Day Subject Data to FDA
- Completion of Phase 1b trial and submission of Final Study Report to FDA

Statement of Benefit to California: Hematologic malignancies in CA affect 19,000 patients/year with an annual mortality of 7,000 and carries a disease burden of ~\$2.1 billion. Meeting the target profile of AB-110 would allow patients to experience: 1) much lower risk for mortality and morbidity; 2) decreased risk for serious, opportunistic infections and severe bleeding; 3) reduction in intensive care unit and in-hospital stay; 4) increased long-term survival rate, and 5) a sustained reduction in long-term relapse rate.

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