IND-enabling development of ART352-L, an endogenous stem cell reactivation therapy to enhance bone healing in the elderly

Grant Award Details

IND-enabling development of ART352-L, an endogenous stem cell reactivation therapy to enhance bone healing in the elderly

Grant Type: Late Stage Preclinical Projects

Grant Number: CLIN1-11256

Project Objective: File an IND application for a clinical trial using ART352-L, an endogenous stem cell reactivation therapy, to enhance bone healing in the elderly.

Investigator:

Name:	Ying Zhu
Institution:	Ankasa Regenerative Therapeutics
Type:	PI

Disease Focus: Bone or Cartilage Disease, Intervertebral disc degeneration

Human Stem Cell Use: Adult Stem Cell

Award Value: $3,994,246

Status: Active

Grant Application Details

Application Title: IND enabling development of ART352-L, an endogenous stem cell reactivation therapy to enhance bone healing in the elderly

Public Abstract:

Therapeutic Candidate or Device

ART352-L, a liposomal formulation of recombinant human WNT3A protein that is intended to enhance the osteogenic properties of autografts in elderly

Indication

Patients with Degenerative Spondylolisthesis (DS) undergoing a spinal fusion surgery

Therapeutic Mechanism

WNT proteins are potent pro-osteogenic signals. L-WNT3A is the investigative prototype material of ART352-L. L-WNT3A treated autografts exhibit enhanced cell survival and reduced apoptosis. As a consequence of osteogenic gene up regulation, the osteogenic properties of the autograft are enhanced: compared to control (untreated) autografts, L-WNT3A treated autografts exhibit a significantly increased new bone formation.

Unmet Medical Need

When the first line therapies with non-surgical approaches fails, patients undergo a spinal fusion procedure, which utilizes an autograft. But autografting is unreliable in older patients. The unmet medical need is an autograft that retains its osteogenic capacity, even in elderly patients.

Project Objective

Initiation of a Phase 1/2 clinical trial

Major Proposed Activities

- Conduct a GLP toxicology study in a rabbit model
- GMP Manufacture of ART352 DS and ART352-L DP to support proposed clinical studies
- Prepare and conduct an Investigational New Drug filing

Statement of Benefit to California:

For Californians over 45, low bone mass diseases are a major public health threat: They account for more days spent in hospital than diabetes and heart attacks, and their related disabilities are greater than those caused by cancers. ART352-L has the potential to dramatically improve bone healing in this older population. Such an improvement in the SOC will result in better outcomes, fewer complications, and a quicker return of older individuals back to the activities of daily living.

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