T89 AMS Phase II study (Clinical trial No: NCT03552263)

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Overview

Acute mountain sickness (AMS) is one of three syndromes of altitude illness. It is very common afflicting up to 60% of travelers who ascend rapidly to >2500 meters above sea level and can seriously impact health quality and cognitive performance. It is a pathological effect of high altitude on humans, caused by acute exposure to low partial pressure of oxygen at high altitude. It presents as a collection of nonspecific symptoms, acquired at high altitude or in low air pressure, including headache and one of the following: gastrointestinal symptoms, fatigue and/or weakness, dizziness/ lightheadedness or difficulty sleeping.

Product Description

In recent years, several literatures and clinical studies have demonstrated that oral administration of T89 may provide substantial benefits in the prevention or alleviation of symptoms associated with AMS. Such effect was also observed in a pilot clinical study recently conducted in Tibet, China.

Safety and Efficacy

Based on previous researches, a prospective, double-blind, randomized, placebo-controlled phase II clinical trial with three arms including T89 low-dose, T89 high-dose and a placebo controlled group was approved in the IND by the US FDA in March 2018, and initiated at University of California, San Francisco (UCSF) in June 2018. This study was to evaluate the efficacy and safety of T89 in healthy population for the prevention or amelioration of symptoms associated with AMS during rapid ascent. Per protocol, a total of 132 subjects were randomized and treated with assigned study drug (either T89 or placebo) for 14 days as pre-treatment before ascending, followed by 5-day treatment at high altitude located at White Mountain Research Center (WMRC) with an elevation of 12,000 feet. During the high-altitude period, all the subjects were assessed by Lake Louise Scoring System (LLSS), Visual Analog Scales (VAS), blood oxygen saturation, and exercise tolerance test.

Developmental Stage

Currently, this Phase II study has been completed and statistical analysis are underway. The study results will be presented to the US FDA during EOP2 meeting and to discuss the design and plan for the subsequent Phase III study.