Fact Sheet for RAD011
Investigational synthetic cannabidiol oral solution (100 mg/ml)

Product Overview

Main Ingredient

Synthetic Cannabidiol

Final Product

• A fully synthetic, man-made molecule having the same chemical structure as botanical extract cannabidiol. No plant or part of the cannabis plant is used in manufacturing process
• Oral solution taken twice daily with food, using a plastic syringe
• Other excipients/ingredients in final product:
  ∗ Medium chain triglycerides (MCT) to dissolve the fat-soluble synthetic powder
  ∗ Vitamin E, a known antioxidant utilized in pharmaceutical product to ensure product stability
  ∗ Saccharin (very low amount) and strawberry flavor to neutralize bitter taste
• The exact mechanism of action of RAD011 is unknown and likely multifactorial (low affinity CB1/2 receptor inverse agonist/antagonist with anxiolytic properties, may inhibit anandamide transporter, may increase mitochondrial biogenesis and metabolism among others)
• Before clinical studies, the product was tested extensively in the Preclinical program:
  ∗ 9 studies in different species/cell lines that lasted from 28 days to 9 months
  ∗ Nonclinical assessment of safety and tolerability has been completed and supports the dose levels selected for SCOUT-015.

• More than 120 individuals have been exposed to RAD011 since 2015:
  ∗ 9 clinical studies were conducted in healthy volunteers, PWS and other CNS indications. Studies lasted from 13 days to 54 weeks with 4 studies completing and others terminated due to previous company insolvency
  ∗ Food effect: absorption of cannabidiol was more consistent and improved when taken with food
  ∗ Ages from 6 months to 55 years old
  ∗ The most common adverse event has been mild to moderate diarrhea

About The Study

SCOUT-015 Synthetic Cannabidiol Oral Solution 015 (NCT #: NCT05098509)
Click here for more information on clinicaltrials.gov

• Global randomized, double-blind, placebo-controlled study in PWS with ~200 patients
• Seamless phase 2/3 design allows for evaluation of multiple dose groups and Intent-To-Treat efficacy analysis with both Phase 2 and Phase 3 cohorts
  Phase 2 objective is to assess safety and tolerability of 3 investigational doses
• Treatment durations and schedule of assessments are the same for both Phase 2 and Phase 3
• An independent Data Monitoring Committee will recommend the dose level/s for the Phase 3 portion of SCOUT-015
• Phase 3 objectives are to assess RAD011 effect on hyperphagia and related behaviors
• Individuals participating in SCOUT-015 may have the opportunity to participate in the open label extension study SCOUT-016

For more information about the SCOUT-015 trial, contact scout015@radiuspharm.com.