Fact Sheet for RAD011

Investigational synthetic cannabidiol oral solution (100 mg/ml)

Product Overview

Main Ingredient

Synthetic Cannabidiol

Final Product

- Does NOT contain alcohol
- Does NOT contain any detectable amount of THC
- Does NOT contain any other psychoactive/ controlled substances
- DEA confirmed that a product that does not contain THC or any other controlled substance is NOT controlled under the Controlled Substance Act (CSA)

- 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.

- 180 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 2 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**

Contact scout015@radiuspharm.com for more information.