Protocol Title: Efficacy and Safety Study of PT150 (formerly ORG 34517) in Veterans with Comorbid Post-Traumatic Stress Disorder (PTSD) and Alcohol Use Disorder (AUD)

Objective: To test the efficacy, safety, and tolerability of PT150 for PTSD and AUD dual diagnosis treatment.

Hypothesis: We hypothesize that veterans taking PT150 compared to placebo will show significantly greater extinction recall, an improvement in PTSD and AUD symptoms over the time course of the study, and that PT150 will be safe and well tolerated.

Primary Inclusion Criteria: Veterans with co-occurring PTSD and AUD.

Subject Completion Target: n = 40 subjects (20 study drug, 20 placebo)

Study Protocol:

Screening: Subjects are pre-screened by phone and at a first study visit. Prior to initiation of the in-person screen, subjects complete an alcohol breathalyzer test to determine breath alcohol concentration (BAC). Subjects must have a BAC of 0.00 before written informed consent can be given. Subjects are screened for primary inclusion criteria and contraindications (exclusion criteria). Eligible subjects complete a packet of self-assessments, report personal and family medical history, receive a physical/neurologic exam, and provide blood/urine samples. Ineligible or uninterested subjects are referred to clinical care.
Total estimated time per subject for screening: 6-12 hours

Testing: This outpatient clinical trial consists of 14±4 days of treatment with study drug, followed by a 14-day follow-up drug-free observation period. Subjects complete the Clinician Administered PTSD Scale (CAPS) and Yale Craving Questionnaire (YCQ) to provide measurements of the study drug's effect on PTSD and AUD symptoms, respectively. Subjects provide Fear-Potentiated Startled (FPS) responses and blood samples for phosphatidylethanol analysis as surrogate measures of study drug efficacy. Safety endpoints, adverse events (AEs), vital signs, and laboratory measures are tracked for each subject to assess study drug safety.
Total estimated time for testing: 28 days

Study Drug: 900 mg of PT150 will be given as a single, fixed, daily dose, per os (PO, by mouth). PT150 is a novel, selective Glucocorticoid Receptor (GR) antagonist. Pop Test Oncology LLC holds the IND for administration of PT150 for this protocol.

Projected Study Timeline: Pending until completion of first study, AS140023-A3b Baker Clinical Trial (Alcohol Interaction Study).