Protocol Title: PT150 (formerly ORG 34517) as a Potential Treatment for Alcohol Dependence – Alcohol Interaction Study

Objective: To evaluate the safety of study drug PT150 taken concurrently with alcohol consumption by comparing safety endpoints following an alcohol challenge prior to and concurrent with PT150 treatment.

Hypothesis: We hypothesize that PT150 will not significantly alter pharmacodynamic measures and be safe and well-tolerated under conditions of alcohol consumption.

Primary Inclusion Criteria: Non-treatment seeking veterans of any race or ethnicity, including both males and females who are post-menopausal, infertile and not hormone cycling, or using approved contraception.

Subject Completion Target: n = 10 subjects

Study Protocol:

Screening: Subjects provide verbal consent prior to pre-screening by phone and at a first study visit. Prior to initiation of the in-person screen, subjects provide written informed consent. Subjects complete an alcohol breathalyzer test to determine breath alcohol concentration (BAC) and must have a BAC of 0.00 before screening assessments can begin. Subjects are screened for primary inclusion criteria and contraindications (exclusion criteria). Ineligible or uninterested subjects are assisted in gaining access to local services.
Total estimated time per subject for screening: 6-12 hours

Testing: Subjects undergo two alcohol challenges on day 1 separated by 4 hours (one with alcohol and one with placebo beverage, randomly ordered). After alcohol challenges on day 1, subjects receive active study drug from days 1-5. On day 5, the study drug dosing is followed by two more alcohol challenges. Physiological measures, subjective and psychometric effects of alcohol, and breath alcohol levels (BAL) are obtained after the alcohol challenges. Subjects are discharged on day 6. For females, a follow-up visit is scheduled to occur at least 14 days after the final dose of study drug to ensure pregnancy does not occur. Adverse events will be tracked for all subjects.
Total estimated time for testing: 7-19 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:

Meeting & setup discussion: *March 2016 – August 2016*
Begin contract & IRB process: *November 2016 – February 2018*
Subject enrollment period: *May 2018 – August 2018*