

August/September 2026

MEDPACE

Clinical Pharmacology

D-4517-005: Cohort 1

C1 Dates:

Study Inpatient Dates:

August 11 –13, 2026

August 25-27, 2026

OPV dates:

August 14, 15, 19, 28, 29 2026

September: 2 & 9, 2026

F/u Phone Call:

August: 16, 20, 23, 30

Instructions / Restrictions:

- Avoid use of prescribed (except hormonal contraceptives and acetaminophen) or over-the-counter medications (except non-steroidal anti-inflammatory drugs (e.g., ibuprofen or naproxen), acetaminophen, or antihistamines may be considered for use during the study on a case-by-case basis by the Investigator) vitamins/herbal supplements **within 7 days prior to Day 1 until completion of Day 29**
- Participants are not permitted to have used any other study drug **within 30 days prior to Day 1/the first dose of study drug until completion of the Day 29 Follow-up Visit**
- You must not have history of alcohol or drug abuse within 1 year prior to screening. You must abstain from alcohol from **48 hours prior to Day –1 Check-In, Day 14 and until end of study**
- You must not be given a vaccine **within 30 days prior to screening; COVID-19 vaccinations within 7 days of Day 1**
- You must agree to not donate sperm **throughout 90 days after administration of the last dose of study drug**
- You must agree to not donate eggs from **start of study and for 90 days after last dose of investigational drug**
- You must refrain from loss or donated greater than or equal to 500 ml of blood or blood products **within 2 months of screening**
- You must abstain from alcohol and drugs **from 48 hours prior to Day –1 Check-In and throughout the study**
- You must abstain from vaping and smoking **within 30 days of screening and during the inpatient stay**
- Continue to follow birth control requirements outlined in the informed consent **30 days prior to the first dose of drug and throughout the study until 30 days following the last dose of study drug for females and 90 days following the last dose for males**

Reminder: breath alcohol & urine drug test at Day –1 and Day 14 Admission

***payment to occur within 48 hours after payment visit day**

Reminder

***payment to occur within 48 hours after payment visit day**

Sun	Mon	Tue	Wed	Thu	Fri	Sat
						1 August
2	3	4	5	6	7	8
9 Begin Alcohol restrictions	10	11 Admission Day –1	12 Dose Day 1	13 Discharge Day 2 *Study Payment #1	14 Outpatient Visit Day 3	15 Outpatient Visit Day 4
16 Day 5 F/U Phone call	17	18	19 Dose & Discharge Day 8 *Study Payment #2	20 Day 9 F/U Phone Call	21	22
23 Begin Alcohol restriction Day 12 F/U Phone call	24	25 Admission Day 14	26 Dose Day 15	27 Discharge Day 16 *Study Payment #3	28 Outpatient Visit Day 17	29 Outpatient Visit Day 18 *Study Payment #4
30 Day 19 F/U Phone call	31	1 September	2 Outpatient Visit Day 22	3	4	5
6	7	8	9 Outpatient Visit Day 29 *Study Payment #5	10	11	12