

STUDY # C3291042

Study Participation Guidelines, Restrictions, and Quick Reference Dates

IMPORTANT!!!

Please follow the guidelines/restrictions below in order to be counted as a qualified participant in the study. Use the dates below as a reference to know when to begin each restriction. Failure to do so may disqualify you.

Guidelines and Restrictions

6 months prior to screening: No excessive alcohol use.

90 days prior to dosing: Females of childbearing potential choosing to use hormonal contraception/birth control pills must begin taking them a minimum of 3 menstrual cycles prior to dosing and continue taking them through 28 days after last dose of study intervention.

60 days prior to dosing: No blood donation.

30 days prior to dosing: Females of childbearing potential choosing to use hormonal intrauterine devices (IUDs) must have the IUD placed a minimum of 1 menstrual cycle prior to dosing and continue to have the IUD in place through 28 days after last dose of study intervention.

30 days prior to dosing: No dosing on any other clinical trial, at any location.

28 days prior to dosing: Stop use of herbal supplements. No products containing marijuana or poppy seeds prior to screening through end of study. Notify physician of **any** medications used within 28 days of check-in.

14 days prior to dosing: Females of childbearing potential using a highly effective, *non-hormonal* form of contraception (includes abstinence) must continue through 28 days after last dose of study intervention.

7 days prior to screening appointments & check-in: Stop use of prescription or nonprescription drugs (including narcotics and non-narcotic analgesics or anti-inflammatories), vitamins, and dietary supplements.

48 hours prior to check-in: Discontinue shaving/hair-removal activities and stop all use of depilatory products. Discontinue use of antiperspirants, lotions, skin creams, hair products, hair gels, or hair oils, fragrances or perfumes or body oils, and avoid excessive exposure to the sun.

48 hours prior to check-in: Stop strenuous activity (heavy lifting [e.g. moving furniture, shoveling snow], weight training, calisthenics, aerobics, etc.).

48 hours prior to check-in and before all screen visits: Stop alcohol use.

24 hours prior to dosing: Stop tobacco and caffeine or xanthine use.

Check-in: Do not bring to the unit any unapproved medications or products containing any form of medication, vitamins, or dietary supplements or you may be disqualified from the study.

Please call the Clinical Research Unit if you are planning on leaving the country at any time before checking in.

Study Schedule

Cohort 1 Group 1

Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
Check-in	Lactic Acid Stinging Test (LAST)	Mon	10DEC2018	8 am		4-hour Fast
-1	Randomize	Tue	11DEC2018	Inpatient		
1 - 3	Dosing Days	Wed -Fri	12DEC2018-14DEC2018	Inpatient		
4	Discharge	Sa	15DEC2018	approximately 10 am	\$990	
Follow-up Phone Call		Tue	15JAN2019	Between 8 am and 4 pm	\$885	
<small>*Planned partial payments may be provided on a loadable debit card or by paper check. Pfizer New Haven Clinical Research Unit reserves the right to determine method of payment. Please know payment amounts may be reduced for missed visits and docking offenses. Refer to the NHCRU House Rules and Informed Consent Document for details.</small>						