

STUDY B7451043

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.

60 days prior to dosing: No blood donation.

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

30 days prior to dosing: Females of childbearing potential choosing to use non-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 investigational product.

28 days prior to dosing: Stop use of hormonal contraception and/or hormone replacement therapy. 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.

7 days prior to dosing: Stop use of prescription or nonprescription drugs or nutritional (dietary) and herbal (including St. John's Wort) supplements. Stop eating/drinking grapefruit or grapefruit-containing products.

7 days prior to dosing: Stop consuming red wine, grapefruit, or grapefruit-related citrus fruits (eg, Seville oranges, pomelos, fruit juices).

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

24 hours prior to check-in: Stop alcohol use.

24 hours prior to dosing: Stop tobacco and caffeine 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 either before checking in or between dosing periods.

Study Schedule
Cohort 1

Part 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	M	17Jun2019	10:00		4-hour Fast
1	Dosing Day (Period 1)	Tu	18Jun2019	Inpatient		
2		W	19Jun2019	Inpatient		
3	Dosing Day (Period 2)	Th	20Jun2019	Inpatient		
4	Dosing Day (Period 2)	Fri	21Jun2019	Inpatient		
5	Dosing Day (Period 2)	Sat	22Jun2019	Inpatient		
6	Dosing Day (Period 2)	Sun	23Jun2019	Inpatient		
7		Mon	24Jun2019	Inpatient		
8	Dosing Day (Period 3)	Tues	25Jun2019	Inpatient		
9	Dosing Day (Period 3)	Wed	26Jun2019	Inpatient		
10	Dosing Day (Period 3)	Th	27Jun2019	Inpatient		
11	Discharge	Fri	28Jun2019	12:00	\$2090	
Follow-up Phone Call		Fri	26Jul2019	Between 8 am and 4 pm	\$1060	

*Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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.