

STUDY # B7981017

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.

6 weeks prior to dosing: No live vaccines (ie, measles, mumps, rubella [MMR], chickenpox, etc.).

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, 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, vitamins, and dietary supplements. Stop eating/drinking grapefruit or grapefruit-containing products. Stop drinking red wine or red wine-containing products.

5 days prior to dosing: Notify the research unit of any fever.

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 and follow-up visit: 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
Sequence 1

Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission P1	Th	03JAN2019	10:00 am		4-hour Fast
1	Dosing P1	F	04JAN2018	Inpatient		
4	Discharge	M	07JAN2019	After discharge procedures	\$780	
-1	Admission P2	Su	13JAN2019	10:00 am		4-hour Fast
1	Dosing P2	M	14JAN2019	Inpatient		
13	Discharge	Sa	26JAN2019	After discharge procedures	\$2935	
Follow-up Phone Call		Th	21FEB2019	Between 8 am and 4 pm	\$935	

*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.

Sequence 2

Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission P1	Th	03JAN2019	10:00 am		4-hour Fast
1	Dosing P1	F	04JAN2019	Inpatient		
13	Discharge P1	W	16JAN2018	After discharge procedures	\$2535	
-1	Admission P2	W	23JAN2019	10: 00 am		4-hour Fast
1	Dosing P2	Th	24JAN2019	Inpatient		
4	Discharge P2	Su	27JAN2019	After discharge procedures	\$1180	
Follow-up Phone Call		Th	21FEB2019	Between 8 am and 4 pm	\$935	

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