

Study Schedule

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.

6 months prior to dosing: No tobacco use.

60 days prior to dosing: No blood donation.

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

28 days prior to dosing: No products containing marijuana or poppy seeds prior to screening through end of study.

14 days prior to dosing: Stop use of prescription or non-prescription drugs (except hormonal contraception) and dietary and herbal supplements. Notify physician of **any** medications used within 14 days of check-in

7 days prior to dosing: Stop eating/drinking grapefruit or grapefruit containing products.

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

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

24 hours prior to dosing: Stop 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 New Haven Pfizer Clinical Research Unit (NHPCRU) if you are planning on leaving the country at any time, either before checking in or between dosing periods.

Study Schedule

Cohort 1 - SubGroup 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission	Sun	02-Dec-2018	10:00		4 Hour Fast
1	Dosing Day	Mon	03-Dec-2018	Inpatient		
2		Tue	04-Dec-2018	Inpatient		
3	Dosing Day	Wed	05-Dec-2018	Inpatient		
4		Thu	06-Dec-2018	Inpatient		
5	Dosing Day	Fri	07-Dec-2018	Inpatient		
6	Discharge	Sat	08-Dec-2018	approximately 12:00	\$1,200 (ClinCard)	
14-Day Follow-up Phone Call		Fri	21-Dec-2018	Between 8am-4pm	\$650 (ClinCard)	
* 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/or docking offenses. Refer to NHPCRU House Rules and Informed Consent document for details.						

Cohort 1 - SubGroup 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission	Mon	03-Dec-2018	12:00		4 Hour Fast
1	Dosing Day	Tue	04-Dec-2018	Inpatient		
2		Wed	05-Dec-2018	Inpatient		
3	Dosing Day	Thu	06-Dec-2018	Inpatient		
4		Fri	07-Dec-2018	Inpatient		
5	Dosing Day	Sat	08-Dec-2018	Inpatient		
6	Discharge	Sun	09-Dec-2018	approximately 12:00	\$1,200 (ClinCard)	
14-Day Follow-up Phone Call		Sat	22-Dec-2018	Between 8am-4pm	\$650 (ClinCard)	
* 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/or docking offenses. Refer to NHPCRU House Rules and Informed Consent document for details.						