

STUDY # B7921028

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 vaccinations (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: 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 non-prescription drugs, vitamins and dietary supplements. Stop use of herbal supplements, hormonal contraception. 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 (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 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

Sub-Group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission Period 1	W	06MAR2019	12:00		4 Hour Fast
1	Dosing Day	Th	07MAR2019	Inpatient		
6	Discharge	Tu	12MAR2019	TBD	\$1,140	
-1	Admission Period 2	Su	17MAR2019	12:00		4 Hour Fast
1	Dosing Day	M	18MAR2019	Inpatient		
13	Discharge	Sat	30MAR2019	TBD	\$2,470	
Follow-up Phone Call		F	26APR2019	Between 8am-4pm	\$1,540	

* 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*

Sub-Group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission Period 1	Th	07MAR2019	12:00		4 Hour Fast
1	Dosing Day	F	08MAR2019	Inpatient		
6	Discharge	W	13MAR2019	TBD	\$1,140	
-1	Admission Period 2	M	18MAR2019	12:00		4 Hour Fast
1	Dosing Day	T	19MAR2019	Inpatient		
13	Discharge	Su	31MAR2019	TBD	\$2,470	

Follow-up Phone Call	Sat	27APR2019	Between 8am-4pm	\$1,540	
<p>* 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*</p>					

APPROVED BY
INTEGREVIEW IRB
JANUARY 24, 2019