

STUDY A8081069

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.

3 months prior to screening: No smoking.

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: Stop use of herbal supplements 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 eating/drinking red wine or red wine-containing products.

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 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

Period 1 Sub-group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Tu	09JUL2019	10:00 am		4-hour Fast
1	Dosing Day	W	10JUL2019	Inpatient		
5	Discharge	Su	14JUL2019	TBD	\$1125	

*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 New Haven CRU House Rules and Informed Consent Document for details.

Period 2 Sub-group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Tu	23JUL2019	10:00 am		4-hour Fast
1	Dosing Day	W	24JUL2019	Inpatient		
5	Discharge	Su	28JUL2019	TBD	\$1125	

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Period 3 Sub-group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Tu	06AUG2019	10:00 am		4-hour Fast
1	Dosing Day	W	07AUG2019	Inpatient		
5	Day 5	Su	11AUG2019	N/A	\$0	

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Period 4 Sub-group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
1	Dosing Day	M	12AUG2019	Inpatient		
2	Discharge	Tu	13AUG2019	TBD	\$1535	

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Period 5 Sub-group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	M	26AUG2019	10:00 am		4-hour Fast
1	Dosing Day	Tu	27AUG2019	Inpatient		
5	Discharge	Sa	31AUG2019	TBD	\$1125	

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Period 6 Sub-group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-5 to -1	Admission Run-in Dosing	Th-M	05SEP2019-09SEP2019	10:00 am		4-hour Fast
1	Dosing Day	Tu	10SEP2019	Inpatient		
5	Discharge	Sa	14SEP2019	approximately 12:00 pm	\$1845	
	Follow-up Phone Call	Tu	08OCT2019	Between 8 am and 4 pm	\$1795	

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Period 1 Sub-group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	W	10JUL2019	10:00 am		4-hour Fast
1	Dosing Day	Th	11JUL2019	Inpatient		
5	Discharge	M	15JUL2019	TBD	\$1025	

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Period 2 Sub-group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	W	24JUL2019	10:00 am		4-hour Fast
1	Dosing Day	Th	25JUL2019	Inpatient		
5	Discharge	M	29JUL2019	approximately 12:00 pm	\$1125	

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Period 3 Sub-group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	W	07AUG2019	10:00 am		4-hour Fast
1	Dosing Day	Th	08AUG2019	Inpatient		
5	Day 5	M	12AUG2019	N/A	\$0	

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Period 4 Sub-group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
1	Dosing Day	Tu	13AUG2019	Inpatient		
2	Discharge	W	14AUG2019	TBD	\$1535	

*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 New Haven CRU House Rules and Informed Consent Document for details.

Period 5 Sub-group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	T	27AUG2019	10:00 am		4-hour Fast
1	Dosing Day	W	28AUG2019	Inpatient		
5	Discharge	Su	01SEP2019	approximately 12:00 pm	\$1125	

*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 New Haven CRU House Rules and Informed Consent Document for details.

Period 6 Sub-group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-5 to -1	Admission/ Run-in Dosing	F-Tu	06SEP2019-10SEP2019	10:00 am		4-hour Fast
1	Dosing Day	W	11SEP2019	Inpatient		
5	Discharge	Su	15SEP2019	approximately 12:00 pm	\$1845	
	Follow-up Phone Call	W	09OCT2019	Between 8 am and 4 pm	\$1795	

*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 New Haven CRU House Rules and Informed Consent Document for details.

Period 1 Sub-group 3						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Tu	16JUL2019	10:00 am		4-hour Fast
1	Dosing Day	W	17JUL2019	Inpatient		
5	Discharge	Su	21JUL2019	TBD	\$1025	

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Period 2 Sub-group 3						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Tu	30JUL2019	10:00 am		4-hour Fast
1	Dosing Day	W	31JUL2019	Inpatient		
5	Discharge	Su	04AUG2019	TBD	\$1125	

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Period 3 Sub-group 3						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Tu	13AUG2019	10:00 am		4-hour Fast
1	Dosing Day	W	14AUG2019	Inpatient		
5	Day 5	Su	18AUG2019	N/A	\$0	

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Period 4 Sub-group 3						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
1	Dosing Day	M	19AUG2019	Inpatient		
2	Discharge	Tu	20AUG2019	TBD	\$1535	

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Period 5 Sub-group 3						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Tu	03SEP2019	10:00 am		4-hour Fast
1	Dosing Day	W	04SEP2019	Inpatient		
5	Discharge	Su	08SEP2019	TBD	\$1125	

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Period 6 Sub-group 3						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-5 to -1	Admission Run-in Dosing	F-Tu	13SEP2019-17SEP2019	10:00 am		4-hour Fast
1	Dosing Day	W	18SEP2019	Inpatient		
5	Discharge	Su	22SEP2019	TBD	\$1845	
	Follow-up Phone Call	W	16OCT2019	Between 8 am and 4 pm	\$1795	

*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 New Haven CRU House Rules and Informed Consent Document for details.