

STUDY # C3651001

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.

28 days prior to dosing: Stop use of herbal supplements. 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.

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 and follow-up visits: Stop caffeine use.

24-hours prior to check-in and until the end of the final follow-up visit: Stop alcohol use.

24-hours prior to check-in: Stop tobacco 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 Group 1 – dosing 2 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Mo	20Aug2018	12:00 noon		4-hour Fast**
1	Dosing Day	Tu	21Aug2018	Inpatient		
2-14	Inpatient	We-Mo	22Aug2018-03Sep2018	Inpatient		
15	Discharge Day 15	Tu	04Sep2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Tu	18Sep2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Tu	02Oct2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Tu	23Oct2018	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***
<p>*Planned partial payments may be provided on a loadable debit card or by paper check. 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> <p>**No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.</p> <p>***No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.</p> <p>****Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.</p>						

Cohort 1 Group 2 – dosing 6 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Th	23Aug2018	12:00 noon		4-hour Fast**
1	Dosing Day	Fr	24Aug2018	Inpatient		
2-14	Inpatient	Sa-Th	25Aug2018-06Sep2018	Inpatient		
15	Discharge Day 15	Fr	07Sep2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Fr	21Sep2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Fr	05Oct2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Tu	23Oct2018	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***
<p>*Planned partial payments may be provided on a loadable debit card or by paper check. 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> <p>**No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.</p> <p>***No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.</p> <p>****Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.</p>						

Study Schedule

Cohort 2 Group 1 – dosing 2 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Th	13Sep2018	12:00 noon		4-hour Fast**
1	Dosing Day	Fr	14Sep2018	Inpatient		
2-14	Inpatient	Sa-Th	15Sep2018-27Sep2018	Inpatient		
15	Discharge Day 15	Fr	28Sep2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Fr	12Oct2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Fr	26Oct2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Fr	16Nov2018	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***
<p>*Planned partial payments may be provided on a loadable debit card or by paper check. 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> <p>**No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.</p> <p>***No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.</p> <p>****Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.</p>						

Cohort 2 Group 2 – dosing 6 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Su	16Sep2018	12:00 noon		4-hour Fast**
1	Dosing Day	Mo	17Sep2018	Inpatient		
2-14	Inpatient	Tu-Su	18Sep2018-30Sep2018	Inpatient		
15	Discharge Day 15	Mo	01Oct2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Mo	15Oct2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Mo	29Oct2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Fr	16Nov2018	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***
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Study Schedule

Cohort 3 Group 1 – dosing 2 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Mo	08Oct2018	12:00 noon		4-hour Fast**
1	Dosing Day	Tu	09Oct2018	Inpatient		
2-14	Inpatient	We-Mo	10Oct2018-22Oct2018	Inpatient		
15	Discharge Day 15	Tu	23Oct2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Tu	06Nov2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Tu	20Nov2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Tu	11Dec2018	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***

*Planned partial payments may be provided on a loadable debit card or by paper check. 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.
****No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.**
*****No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.**
******Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.**

Cohort 3 Group 2 – dosing 6 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Th	11Oct2018	12:00 noon		4-hour Fast**
1	Dosing Day	Fr	12Oct2018	Inpatient		
2-14	Inpatient	Sa-Th	13Oct2018-25Oct2018	Inpatient		
15	Discharge Day 15	Fr	26Oct2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Fr	09Nov2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Mo	26Nov2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Tu	11Dec2018	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***

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****No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.**
*****No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.**
******Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.**

Study Schedule

Cohort 4 Group 1 – dosing 2 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Th	01Nov2018	12:00 noon		4-hour Fast**
1	Dosing Day	Fr	02Nov2018	Inpatient		
2-14	Inpatient	Sa-Th	03Nov2018-15Nov2018	Inpatient		
15	Discharge Day 15	Fr	16Nov2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Fr	30Nov2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Fr	14Dec2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Fr	04Jan2019	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***

*Planned partial payments may be provided on a loadable debit card or by paper check. 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.
****No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.**
*****No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.**
******Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.**

Cohort 4 Group 2 – dosing 6 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Su	04Nov2018	12:00 noon		4-hour Fast**
1	Dosing Day	Mo	05Nov2018	Inpatient		
2-14	Inpatient	Tu-Su	06Nov2018-18Nov2018	Inpatient		
15	Discharge Day 15	Mo	19Nov2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Mo	03Dec2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Mo	17Dec2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Mo	07Jan2019	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***

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****No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.**
*****No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.**
******Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.**

Study Schedule

Cohort 5 Group 1 – dosing 2 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Mo	26Nov2018	12:00 noon		4-hour Fast**
1	Dosing Day	Tu	27Nov2018	Inpatient		
2-14	Inpatient	We-Mo	28Nov2018-10Dec2018	Inpatient		
15	Discharge Day 15	Tu	11Dec2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Th	27Dec2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Tu	08Jan2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Tu	29Jan2019	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***

*Planned partial payments may be provided on a loadable debit card or by paper check. 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.
****No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.**
*****No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.**
******Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.**

Cohort 5 Group 2 – dosing 6 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Th	29Nov2018	12:00 noon		4-hour Fast**
1	Dosing Day	Fr	30Nov2018	Inpatient		
2-14	Inpatient	Sa-Th	01Dec2018-13Dec2018	Inpatient		
15	Discharge Day 15	Fr	14Dec2018	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Th	27Dec2018	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Fr	11Jan2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Tu	29Jan2019	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D85****	N/A	N/A	N/A	N/A	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***

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*****No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.**
******Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.**

Study Schedule

Cohort 6 Group 1 – dosing 2 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Mo	07Jan2019	12:00 noon		4-hour Fast**
1	Dosing Day	Tu	08Jan2019	Inpatient		
2-14	Inpatient	We-Mo	09Jan2019-21Jan2019	Inpatient		
15	Discharge Day 15	Tu	22Jan2019	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Tu	05Feb2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Tu	19Feb2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Tu	12Mar2019	08:30 am	\$550	4-hour Fast***
	Follow-up Visit D85****	Tu	02Apr2019	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***
<p>*Planned partial payments may be provided on a loadable debit card or by paper check. 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> <p>**No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.</p> <p>***No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.</p> <p>****Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.</p>						

Cohort 6 Group 2 – dosing 6 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Th	10Jan2019	12:00 noon		4-hour Fast**
1	Dosing Day	Fr	11Jan2019	Inpatient		
2-14	Inpatient	Sa-Th	12Jan2019-24Jan2019	Inpatient		
15	Discharge Day 15	Fr	25Jan2019	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Fr	08Feb2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Fr	22Feb2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Fr	15Mar2019	08:30 am	\$550	4-hour Fast***
	Follow-up Visit D85****	Tu	02Apr2019	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***
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Study Schedule

Cohort 7 Group 1 – dosing 2 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Th	31Jan2019	12:00 noon		4-hour Fast**
1	Dosing Day	Fr	01Feb2019	Inpatient		
2-14	Inpatient	Sa-Th	02Feb2019-14Feb2019	Inpatient		
15	Discharge Day 15	Fr	15Feb2019	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Fr	01Mar2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Fr	15Mar2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Fr	05Apr2019	08:30 am	\$550	4-hour Fast***
	Follow-up Visit D85****	Fr	26Apr2019	08:30 am	\$550	4-hour Fast***
	Follow-up Visit D113****	Fr	24May2019	08:30 am	\$1,600	4-hour Fast***
<p>*Planned partial payments may be provided on a loadable debit card or by paper check. 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> <p>**No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.</p> <p>***No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.</p> <p>****Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.</p>						

Cohort 7 Group 2 – dosing 6 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Su	03Feb2019	12:00 noon		4-hour Fast**
1	Dosing Day	Mo	04Feb2019	Inpatient		
2-14	Inpatient	Tu-Su	05Feb2019-17Feb2019	Inpatient		
15	Discharge Day 15	Mo	18Feb2019	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Mo	04Mar2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Mo	18Mar2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Mo	08Apr2019	08:30 am	\$550	4-hour Fast***
	Follow-up Visit D85****	Mo	29Apr2019	08:30 am	\$550	4-hour Fast***
	Follow-up Visit D113****	Fr	24May2019	08:30 am	\$1,600	4-hour Fast***
<p>*Planned partial payments may be provided on a loadable debit card or by paper check. 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> <p>**No alcohol, caffeine, or tobacco for at least 24 hours prior to check-in.</p> <p>***No alcohol until after the final follow-up visit and No caffeine for at least 24 hours prior to each follow-up visit.</p> <p>****Additional follow-up visits may be required based on data collected at prior follow-up visits. You will be paid an additional \$250 dollars for any additional follow-up visits.</p>						

Study Schedule

Cohort 8/JClin Group 1 – dosing 5 volunteers						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Mo	14Jan2019	12:00 noon		4-hour Fast**
1	Dosing Day	Tu	15Jan2019	Inpatient		
2-14	Inpatient	We-Mo	16Jan2019-28Jan2019	Inpatient		
15	Discharge Day 15	Tu	29Jan2019	approximately 12:00 noon	\$3,000	
	Planned Follow-up Visit D29	Tu	12Feb2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D43	Tu	26Feb2019	08:30 am	\$450	4-hour Fast***
	Planned Follow-up Visit D64	Tu	19Mar2019	08:30 am	\$550	4-hour Fast***
	Follow-up Visit D85****	Tu	09Apr2019	08:30 am	\$1,500	4-hour Fast***
	Follow-up Visit D113****	N/A	N/A	N/A	N/A	4-hour Fast***

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