

Compound: PF-07302048; Protocol: C4591001

Reason(s) for Narrative: HIV

Unique Subject ID: C4591001 1226 12262255; Country: Brazil

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 16OCT2020; Date of Last Dose: 06NOV2020

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1972	48	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
173.8 cm	95.6 kg	31.6 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
HIV	HIV test positive	2010	Present
Obesity	Obesity	2010	Present
contact dermatitis	Dermatitis contact	2017	Present

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Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	16OCT2020 (1)	14:00
2	BNT162b2	06NOV2020 (22)	12:22

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Chills	Chills	06NOV2020 (22)	23:00	08NOV2020 (24)	
2	GENRL	Injection site pain	Pain at the injection site	06NOV2020 (22)	23:00	08NOV2020 (24)	
3	MUSC	Myalgia	Muscle pain	06NOV2020 (22)	23:00	08NOV2020 (24)	
4	MUSC	Myalgia	muscle pain	19OCT2020 (4)		22OCT2020 (7)	
5	GASTR	Nausea	Nauseas	06NOV2020 (22)	23:00	08NOV2020 (24)	
6	GENRL	Pyrexia	Fever 39 C	06NOV2020 (22)	23:00	08NOV2020 (24)	
7	GASTR	Vomiting	Vomiting	06NOV2020 (22)	23:00	08NOV2020 (24)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	3	N	N	Resolved (08NOV2020)	Study Treatment	2	1	N
2	3	3	N	N	Resolved (08NOV2020)	Study Treatment	2	1	N

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Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	3	3	TC	N	Resolved (08NOV2020)	Study Treatment	2	1	N
4	4	2	TC	N	Resolved (22OCT2020)	Study Treatment	1	4	N
5	3	3	N	N	Resolved (08NOV2020)	Study Treatment	2	1	N
6	3	3	TC	N	Resolved (08NOV2020)	Study Treatment	2	1	N
7	3	3	TC	N	Resolved (08NOV2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	
Completed	VACCINATION	06JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

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