Clinical trial results:
A Phase 2, Randomized, Double-Blind, Placebo Controlled, Dose Ranging, Dose Finding, Parallel Group Study to Assess Efficacy and Safety of PF-07081532, And Open Label Oral Semaglutide, In Adults with Type 2 Diabetes Mellitus (T2DM) Inadequately Controlled on Metformin, And Separately PF-07081532 Compared to Matching Placebo in Adults with Obesity but Without T2DM.

Summary

EudraCT number	2022-002834-15
Trial protocol	CZ HU BG
Global end of trial date	22 September 2023

Results information

Result version number	v1 (current)
This version publication date	27 September 2024
First version publication date	27 September 2024

Trial information

Trial identification

Sponsor protocol code	C3991004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05579977
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 January 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 September 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of a range of PF-07081532 doses compared to placebo, in subjects with T2DM inadequately controlled on metformin and subjects with obesity but without T2DM.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 October 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 95
Country: Number of subjects enrolled	Czechia: 22
Country: Number of subjects enrolled	Hungary: 90
Country: Number of subjects enrolled	Japan: 97
Country: Number of subjects enrolled	Puerto Rico: 29
Country: Number of subjects enrolled	Bulgaria: 34
Country: Number of subjects enrolled	Poland: 89
Country: Number of subjects enrolled	United States: 445
Worldwide total number of subjects	901
EEA total number of subjects	235

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	683
From 65 to 84 years	218
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study had 2 cohorts: Cohort 1 included subjects with type 2 diabetes mellitus (T2DM) on a background therapy of metformin. Cohort 2 included subjects with obesity But without T2DM.

Pre-assignment

Screening details:

A total of 902 subjects were randomized in this study of which 1 subject did not receive treatment. The study was terminated based on pharmacokinetic data from Phase 1 drug-drug-interaction studies and laboratory measurements of elevated transaminases in these Phase 1 studies as well as this Phase 2 study.

Period 1

Period 1 title	Treatment Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo (T2DM)

Arm description:

Subjects randomized to receive a single dose of PF-07081532-matching placebo once daily (QD) orally.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo tablets orally QD.

Arm title	PF-07081532 20mg (T2DM)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD orally.

Arm type	Experimental
Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	PF-07081532 40mg (T2DM)

Arm description:

Subjects with T2DM inadequately controlled with metformin were administered PF-07081532 20 mg QD orally for 4 weeks followed by PF-07081532 40 mg QD orally.

Arm type	Experimental

Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	PF-07081532 80mg (T2DM)

Arm description:

Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks each followed by PF-07081532 80 mg QD orally.

Arm type	Experimental
Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	PF-07081532 160mg (T2DM)

Arm description:

Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD 40 mg QD, 60 mg QD, 80 mg QD and 120 mg QD orally for 4 weeks each followed by PF-07081532 160 mg QD orally.

Arm type	Experimental
Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	PF-07081532 260mg (T2DM)

Arm description:

Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD, 80 mg QD, 140 mg QD and 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.

Arm type	Experimental
Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	Rybelsus 14mg (T2DM)

Arm description:

Subjects with T2DM inadequately controlled with metformin were administered titrating doses of Rybelsus 3 mg QD and 7 mg QD each for 4 weeks followed by 14 mg QD.

Arm type	Experimental
Investigational medicinal product name	Rybelsus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Rybelsus was available as tablets at unit dose strength of 3, 7 and 14 mg to be administered orally QD at the desired dose levels.

Arm title	Placebo (Obesity)

Arm description:

Subjects randomized to receive a single dose of PF-07081532-matching placebo QD orally.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo tablets orally QD.

Arm title	PF-07081532 80mg (Obesity)

Arm description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks each followed by PF-07081532 80 mg QD orally.

Arm type	Experimental
Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	PF-07081532 140mg (Obesity)

Arm description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 80 mg QD, 120 mg QD orally for 4 weeks each followed by PF-07081532 140 mg QD orally.

Arm type	Experimental
Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	PF-07081532 200mg (Obesity,5 steps)

Arm description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 100 mg QD, 160 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.

Arm type	Experimental

Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	PF-07081532 200mg (Obesity,4 steps)

Arm description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.

Arm type	Experimental
Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Arm title	PF-07081532 260mg (Obesity)

Arm description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD, 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.

Arm type	Experimental
Investigational medicinal product name	PF-07081532
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-07081532 was available as tablets at unit dose strength of 20, 60 and 100 mg to be administered orally QD at the desired dose levels.

Number of subjects in period 1	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)
Started	75	73	72
Completed	0	0	0
Not completed	75	73	72
Consent withdrawn by subject	2	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	3	11
Death	1	-	-
Pregnancy	-	-	-
Study terminated by sponsor	70	70	61
Unspecified	-	-	-

Lost to follow-up	-	-	-
Treatment with restricted medication needed	2	-	-

Number of subjects in period 1	PF-07081532 80mg (T2DM)	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)
Started	73	72	74
Completed	0	0	0
Not completed	73	72	74
Consent withdrawn by subject	1	2	-
Physician decision	-	-	-
Adverse event, non-fatal	10	5	17
Death	-	-	-
Pregnancy	-	-	-
Study terminated by sponsor	59	63	53
Unspecified	2	1	2
Lost to follow-up	1	1	1
Treatment with restricted medication needed	-	-	1

Number of subjects in period 1	Rybelsus 14mg (T2DM)	Placebo (Obesity)	PF-07081532 80mg (Obesity)
Started	73	64	66
Completed	0	0	0
Not completed	73	64	66
Consent withdrawn by subject	1	8	3
Physician decision	-	-	-
Adverse event, non-fatal	5	5	12
Death	-	-	-
Pregnancy	-	-	-
Study terminated by sponsor	66	48	47
Unspecified	1	2	2
Lost to follow-up	-	1	2
Treatment with restricted medication needed	-	-	-

Number of subjects in period 1	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)	PF-07081532 200mg (Obesity,4 steps)
Started	64	65	66
Completed	0	0	0
Not completed	64	65	66
Consent withdrawn by subject	3	5	1
Physician decision	-	-	1
Adverse event, non-fatal	20	15	24
Death	-	-	-
Pregnancy	1	-	-

Study terminated by sponsor	37	44	36
Unspecified	1	-	-
Lost to follow-up	2	1	4
Treatment with restricted medication needed	-	-	-

Number of subjects in period 1	PF-07081532 260mg (Obesity)
Started	64
Completed	0
Not completed	64
Consent withdrawn by subject	3
Physician decision	-
Adverse event, non-fatal	23
Death	-
Pregnancy	-
Study terminated by sponsor	32
Unspecified	3
Lost to follow-up	3
Treatment with restricted medication needed	-

Period 2	
Period 2 title	Follow up Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	Placebo (T2DM)

Arm description:

Subjects randomized to receive a single dose of PF-07081532-matching placebo once daily (QD) orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 20mg (T2DM)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 40mg (T2DM)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD orally for 4 weeks, followed by 40 mg QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 80mg (T2DM)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks, followed by PF-07081532 80 mg QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 160mg (T2DM)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD 40 mg QD, 60 mg QD, 80 mg QD and 120 mg QD orally for 4 weeks, followed by PF-07081532 160 mg QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 260mg (T2DM)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD, 80 mg QD, 140 mg QD and 200 mg QD orally for 4 weeks, followed by PF-07081532 260 mg QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Rybelsus 14mg (T2DM)

Arm description:

Subjects randomized to receive Rybelsus 3 mg QD and 7 mg QD each for 4 weeks followed by 14 mg QD.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Placebo (Obesity)

Arm description:

Subjects randomized to receive a single dose of PF-07081532-matching placebo QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 80mg (Obesity)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks, followed by PF-07081532 80 mg QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 140mg (Obesity)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 80 mg QD,120 mg QD orally for 4 weeks each followed by PF-07081532 140 mg QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 200mg (Obesity,5 steps)

Arm description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 100 mg QD,160 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	PF-07081532 200mg (Obesity,4 steps)

Arm description:	
Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	PF-07081532 260mg (Obesity)
Arm description:	
Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD, 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)
Started	75	73	72
Completed	72	73	72
Not completed	3	0	0
Consent withdrawn by subject	2	-	-
Death	1	-	-
Lost to follow-up	-	-	-

Number of subjects in period 2	PF-07081532 80mg (T2DM)	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)
Started	73	72	74
Completed	72	70	72
Not completed	1	2	2
Consent withdrawn by subject	-	1	-
Death	-	-	-
Lost to follow-up	1	1	2

Number of subjects in period 2	Rybelsus 14mg (T2DM)	Placebo (Obesity)	PF-07081532 80mg (Obesity)
Started	73	64	66
Completed	71	59	61
Not completed	2	5	5
Consent withdrawn by subject	1	4	2
Death	-	-	-
Lost to follow-up	1	1	3

Number of subjects in period 2	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)	PF-07081532 200mg (Obesity,4 steps)
Started	64	65	66
Completed	59	60	61
Not completed	5	5	5
Consent withdrawn by subject	3	3	1
Death	-	-	-

Lost to follow-up	2	2	4

Number of subjects in period 2	PF-07081532 260mg (Obesity)
Started	64
Completed	57
Not completed	7
Consent withdrawn by subject	3
Death	-
Lost to follow-up	4

Baseline characteristics

Reporting groups

Reporting group title	Placebo (T2DM)
Reporting group description:	
Subjects randomized to receive a single dose of PF-07081532-matching placebo once daily (QD) orally.	
Reporting group title	PF-07081532 20mg (T2DM)
Reporting group description:	
Subjects randomized to receive PF-07081532 20 mg QD orally.	
Reporting group title	PF-07081532 40mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered PF-07081532 20 mg QD orally for 4 weeks followed by PF-07081532 40 mg QD orally.	
Reporting group title	PF-07081532 80mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks each followed by PF-07081532 80 mg QD orally.	
Reporting group title	PF-07081532 160mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD 40 mg QD, 60 mg QD, 80 mg QD and 120 mg QD orally for 4 weeks each followed by PF-07081532 160 mg QD orally.	
Reporting group title	PF-07081532 260mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD, 80 mg QD, 140 mg QD and 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.	
Reporting group title	Rybelsus 14mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered titrating doses of Rybelsus 3 mg QD and 7 mg QD each for 4 weeks followed by 14 mg QD.	
Reporting group title	Placebo (Obesity)
Reporting group description:	
Subjects randomized to receive a single dose of PF-07081532-matching placebo QD orally.	
Reporting group title	PF-07081532 80mg (Obesity)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks each followed by PF-07081532 80 mg QD orally.	
Reporting group title	PF-07081532 140mg (Obesity)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 80 mg QD, 120 mg QD orally for 4 weeks each followed by PF-07081532 140 mg QD orally.	
Reporting group title	PF-07081532 200mg (Obesity,5 steps)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 100 mg QD, 160 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.	
Reporting group title	PF-07081532 200mg (Obesity,4 steps)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.	
Reporting group title	PF-07081532 260mg (Obesity)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD, 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.	

Reporting group values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)
Number of subjects	75	73	72
Age Categorical Units: Subjects			
Less than (<) 18 years	0	0	0
18-44 years	6	8	3
45-64 years	40	39	52
More than equal to (>=) 65 years	29	26	17
Age continuous Units: years			
geometric mean	60.0	58.8	58.6
standard deviation	± 10.17	± 10.17	± 8.47
Sex: Female, Male Units: Subjects			
Female	42	30	29
Male	33	43	43
Race Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	12	14	17
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	2	4
White	58	57	51
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	14	13	8
Not Hispanic or Latino	61	60	63
Unknown or Not Reported	0	0	1

Reporting group values	PF-07081532 80mg (T2DM)	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)
Number of subjects	73	72	74
Age Categorical Units: Subjects			
Less than (<) 18 years	0	0	0
18-44 years	4	4	6
45-64 years	48	44	36
More than equal to (>=) 65 years	21	24	32
Age continuous Units: years			
geometric mean	57.7	59.6	60.3
standard deviation	± 9.21	± 9.71	± 9.76
Sex: Female, Male Units: Subjects			
Female	31	33	31
Male	42	39	43

Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	15	13	14
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	5	5
White	54	54	54
More than one race	0	0	0
Unknown or Not Reported	0	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	7	14	10
Not Hispanic or Latino	66	58	64
Unknown or Not Reported	0	0	0

Reporting group values	Rybelsus 14mg (T2DM)	Placebo (Obesity)	PF-07081532 80mg (Obesity)
Number of subjects	73	64	66
Age Categorical Units: Subjects			
Less than (<) 18 years	0	0	0
18-44 years	5	17	25
45-64 years	43	36	33
More than equal to (>=) 65 years	25	11	8
Age continuous Units: years			
geometric mean	59.8	50.9	49.3
standard deviation	± 8.89	± 13.30	± 12.97
Sex: Female, Male Units: Subjects			
Female	36	36	38
Male	37	28	28
Race Units: Subjects			
American Indian or Alaska Native	0	1	1
Asian	11	4	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	4	6
White	57	55	56
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	8	5	8
Not Hispanic or Latino	64	59	58
Unknown or Not Reported	1	0	0

Reporting group values	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)	PF-07081532 200mg (Obesity,4 steps)
Number of subjects	64	65	66

Age Categorical Units: Subjects			
Less than (<) 18 years	0	0	0
18-44 years	24	25	21
45-64 years	35	34	39
More than equal to (>=) 65 years	5	6	6
Age continuous Units: years			
geometric mean	48.1	47.6	50.0
standard deviation	± 12.44	± 13.49	± 10.74
Sex: Female, Male Units: Subjects			
Female	45	36	42
Male	19	29	24
Race Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	3	3	4
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	15	6	5
White	44	56	55
More than one race	0	0	1
Unknown or Not Reported	0	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	10	14	12
Not Hispanic or Latino	54	51	54
Unknown or Not Reported	0	0	0

Reporting group values	PF-07081532 260mg (Obesity)	Total	
Number of subjects	64	901	
Age Categorical Units: Subjects			
Less than (<) 18 years	0	0	
18-44 years	23	171	
45-64 years	33	512	
More than equal to (>=) 65 years	8	218	
Age continuous Units: years			
geometric mean	48.5		
standard deviation	± 11.68	-	
Sex: Female, Male Units: Subjects			
Female	40	469	
Male	24	432	
Race Units: Subjects			
American Indian or Alaska Native	1	5	
Asian	6	119	

Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	4	69	
White	52	703	
More than one race	1	2	
Unknown or Not Reported	0	2	
Ethnicity Units: Subjects			
Hispanic or Latino	10	133	
Not Hispanic or Latino	54	766	
Unknown or Not Reported	0	2	

End points reporting groups

Reporting group title	Placebo (T2DM)
Reporting group description:	
Subjects randomized to receive a single dose of PF-07081532-matching placebo once daily (QD) orally.	
Reporting group title	PF-07081532 20mg (T2DM)
Reporting group description:	
Subjects randomized to receive PF-07081532 20 mg QD orally.	
Reporting group title	PF-07081532 40mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered PF-07081532 20 mg QD orally for 4 weeks followed by PF-07081532 40 mg QD orally.	
Reporting group title	PF-07081532 80mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks each followed by PF-07081532 80 mg QD orally.	
Reporting group title	PF-07081532 160mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD 40 mg QD, 60 mg QD, 80 mg QD and 120 mg QD orally for 4 weeks each followed by PF-07081532 160 mg QD orally.	
Reporting group title	PF-07081532 260mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD, 80 mg QD, 140 mg QD and 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.	
Reporting group title	Rybelsus 14mg (T2DM)
Reporting group description:	
Subjects with T2DM inadequately controlled with metformin were administered titrating doses of Rybelsus 3 mg QD and 7 mg QD each for 4 weeks followed by 14 mg QD.	
Reporting group title	Placebo (Obesity)
Reporting group description:	
Subjects randomized to receive a single dose of PF-07081532-matching placebo QD orally.	
Reporting group title	PF-07081532 80mg (Obesity)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks each followed by PF-07081532 80 mg QD orally.	
Reporting group title	PF-07081532 140mg (Obesity)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 80 mg QD, 120 mg QD orally for 4 weeks each followed by PF-07081532 140 mg QD orally.	
Reporting group title	PF-07081532 200mg (Obesity,5 steps)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 100 mg QD, 160 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.	
Reporting group title	PF-07081532 200mg (Obesity,4 steps)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.	
Reporting group title	PF-07081532 260mg (Obesity)
Reporting group description:	
Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 80	

mg QD, 140 mg QD, 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.

Reporting group title	Placebo (T2DM)

Reporting group description:

Subjects randomized to receive a single dose of PF-07081532-matching placebo once daily (QD) orally.

Reporting group title	PF-07081532 20mg (T2DM)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD orally.

Reporting group title	PF-07081532 40mg (T2DM)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD orally for 4 weeks, followed by 40 mg QD orally.

Reporting group title	PF-07081532 80mg (T2DM)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks, followed by PF-07081532 80 mg QD orally.

Reporting group title	PF-07081532 160mg (T2DM)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD 40 mg QD, 60 mg QD, 80 mg QD and 120 mg QD orally for 4 weeks, followed by PF-07081532 160 mg QD orally.

Reporting group title	PF-07081532 260mg (T2DM)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD, 80 mg QD, 140 mg QD and 200 mg QD orally for 4 weeks, followed by PF-07081532 260 mg QD orally.

Reporting group title	Rybelsus 14mg (T2DM)

Reporting group description:

Subjects randomized to receive Rybelsus 3 mg QD and 7 mg QD each for 4 weeks followed by 14 mg QD.

Reporting group title	Placebo (Obesity)

Reporting group description:

Subjects randomized to receive a single dose of PF-07081532-matching placebo QD orally.

Reporting group title	PF-07081532 80mg (Obesity)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks, followed by PF-07081532 80 mg QD orally.

Reporting group title	PF-07081532 140mg (Obesity)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 80 mg QD,120 mg QD orally for 4 weeks each followed by PF-07081532 140 mg QD orally.

Reporting group title	PF-07081532 200mg (Obesity,5 steps)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 100 mg QD,160 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.

Reporting group title	PF-07081532 200mg (Obesity,4 steps)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.

Reporting group title	PF-07081532 260mg (Obesity)

Reporting group description:

Subjects randomized to receive PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD, 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.

Subject analysis set title	Placebo (T2DM
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with T2DM inadequately controlled with metformin were administered PF-07081532-matching placebo once daily (QD) orally.

Subject analysis set title	PF-07081532 40 mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 40 mg QD orally were included.	
Subject analysis set title	PF-07081532 60mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 60 mg QD orally were included.	
Subject analysis set title	PF-07081532 80 mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
randomized to receive PF-07081532 80 mg QD orally were included.	
Subject analysis set title	PF-07081532 120 mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 120 mg QD orally were included.	
Subject analysis set title	PF-07081532 140mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 140 mg QD orally were included.	
Subject analysis set title	PF-07081532 200mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 200 mg QD orally were included.	
Subject analysis set title	PF-07081532 260 mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 260 mg QD orally were included.	
Subject analysis set title	Rybelsus 3mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive Rybelsus 3 mg QD orally were included.	
Subject analysis set title	Rybelsus 7mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive Rybelsus 7 mg QD orally were included.	
Subject analysis set title	PF-07081532 20mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 20 mg QD orally were included.	
Subject analysis set title	PF-07081532 40 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 40 mg QD orally were included.	
Subject analysis set title	PF-07081532 60 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 60 mg QD orally were included.	
Subject analysis set title	PF-07081532 100 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 100 mg QD orally were included.	

Subject analysis set title	PF-07081532 120 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 120 mg QD orally were included.	
Subject analysis set title	PF-07081532 160 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 160 mg QD orally were included.	
Subject analysis set title	PF-07081532 200 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 200 mg QD orally were included.	
Subject analysis set title	PF-07081532 260 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 260 mg QD orally were included.	
Subject analysis set title	PF-07081532 160 mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 160 mg QD orally were included.	
Subject analysis set title	Rybelsus 14 mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive Rybelsus 14 mg QD orally were included.	
Subject analysis set title	PF-07081532 80 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 80 mg QD orally were included.	
Subject analysis set title	PF-07081532 140 mg (Obesity)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 140 mg QD orally were included.	
Subject analysis set title	PF-07081532 20mg (T2DM)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects randomized to receive PF-07081532 20 mg QD orally were included.	

Primary: Placebo-adjusted, Change From Baseline in Percentage of Glycated Hemoglobin (HbA1c) at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Placebo-adjusted, Change From Baseline in Percentage of Glycated Hemoglobin (HbA1c) at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)[1][2]
End point description:	
Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.	
End point type	Primary
End point timeframe:	
Baseline (result closest prior to dosing on Day 1), Week 32	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis was not planned for this endpoint

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[3]	0[4]	0[5]	0[6]
Units: Percentage of HbA1c				
least squares mean (standard error)	()	()	()	()

Notes:

[3] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[4] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[5] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[6] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[7]	0[8]	0[9]	
Units: Percentage of HbA1c				
least squares mean (standard error)	()	()	()	

Notes:

[7] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[8] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[9] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Primary: Placebo-adjusted, Percent Change From Baseline in Body Weight at Week 32: Cohort 2 (Obesity)

End point title	Placebo-adjusted, Percent Change From Baseline in Body Weight at Week 32: Cohort 2 (Obesity)[10][11]

End point description:

Body weight was measured using a calibrated weighing scale. Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.

End point type	Primary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis was not planned for this endpoint

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[12]	0[13]	0[14]	0[15]
Units: Percent change				
least squares mean (standard error)	()	()	()	()

Notes:

[12] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[13] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[14] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[15] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[16]	0[17]		
Units: Percent change				
least squares mean (standard error)	()	()		

Notes:

[16] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[17] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved HbA1C <7% at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Percentage of Subjects who Achieved HbA1C <7% at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)[18]

End point description:

Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[19]	0[20]	0[21]	0[22]
Units: Percentage of subjects				
number (not applicable)				

Notes:

[19] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[20] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[21] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[22] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[23]	0[24]	0[25]	
Units: Percentage of subjects				
number (not applicable)				

Notes:

[23] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[24] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[25] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fasting Plasma Glucose (FPG) at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)[26]

End point description:

Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[27]	0[28]	0[29]	0[30]
Units: milligrams per deciliter (mg/dL)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[27] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[28] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[29] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[30] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[31]	0[32]	0[33]	
Units: milligrams per deciliter (mg/dL)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[31] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[32] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[33] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Body Weight at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Percent Change From Baseline in Body Weight at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)[34]

End point description:

Body weight was measured using a calibrated weighing scale. Data was not collected for Week 32 as the study was terminated prior to any subject reaching Week 32.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[35]	0[36]	0[37]	0[38]
Units: Percent change				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[35] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[36] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[37] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[38] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[39]	0[40]	0[41]	
Units: Percent change				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[39] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[40] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[41] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Placebo-adjusted, Change From Baseline in HbA1C in the Rybelsus arm at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Placebo-adjusted, Change From Baseline in HbA1C in the Rybelsus arm at Week 32: Cohort 1 (Type 2 Diabetes Mellitus)[42]

End point description:

Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32. This endpoint was planned to be analyzed only for rybelsus arm and placebo arm as pre-specified in the protocol.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	Rybelsus 14mg (T2DM)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[43]	0[44]		
Units: Percentage of HbA1c				
arithmetic mean (standard deviation)	()	()		

Notes:

[43] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[44] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving >=5%, >=10%, and >=15% Body Weight Loss at Week 32 Relative to Baseline: Cohort 2 (Obesity)

End point title	Percentage of Subjects Achieving >=5%, >=10%, and >=15% Body Weight Loss at Week 32 Relative to Baseline: Cohort 2 (Obesity)[45]

End point description:

Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[46]	0[47]	0[48]	0[49]
Units: Percentage of subjects				
number (not applicable)				

Notes:

[46] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[47] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[48] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[49] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[50]	0[51]		
Units: Percentage of subjects				
number (not applicable)				

Notes:

[50] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[51] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Waist Circumference at Week 32: Cohort 2 (Obesity)

End point title	Absolute Change From Baseline in Waist Circumference at Week 32: Cohort 2 (Obesity)[52]

End point description:

Waist circumference was measured at midpoint, between lower margin of last palpable rib and top of iliac crest (approximately 1 inch [2.54 centimeter {cm}] above the navel). It was measured by using an anthropometric tape (stretch-resistant). Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[53]	0[54]	0[55]	0[56]
Units: Centimeter				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[53] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[54] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[55] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[56] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 200mg	PF-07081532 260mg		

	(Obesity,4 steps)	(Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[57]	0[58]		
Units: Centimeter				
arithmetic mean (standard deviation)	()	()		

Notes:

[57] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[58] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Waist-to-hip Ratio at Week 32: Cohort 2 (Obesity)

End point title	Absolute Change From Baseline in Waist-to-hip Ratio at Week 32: Cohort 2 (Obesity)[59]

End point description:

The hip circumference was defined as the circumference around the widest portion of the buttocks. Waist circumference was measured at midpoint, between lower margin of last palpable rib and top of iliac crest (approximately 1 inch [2.54 cm] above the navel). The measurements were performed using an anthropometric tape (stretch-resistant). Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)	PF-07081532 200mg (Obesity,4 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[60]	0[61]	0[62]	0[63]
Units: Ratio				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[60] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[61] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[62] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[63] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 260mg (Obesity)			
Subject group type	Reporting group			
Number of subjects analysed	0[64]			
Units: Ratio				
arithmetic mean (standard deviation)	()			

Notes:

[64] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) at Week 32: Cohort 2 (Obesity)

End point title	Change From Baseline in Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) at Week 32: Cohort 2 (Obesity)[65]

End point description:

HOMA-IR was calculated as: fasting plasma insulin ([FPI]*(FPG)/405 and measured in terms of mg/dL* (milliunits per liter). Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[66]	0[67]	0[68]	0[69]
Units: Mg/dL* (milliunits per liter)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[66] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[67] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[68] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[69] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[70]	0[71]		
Units: Mg/dL* (milliunits per liter)				
arithmetic mean (standard deviation)	()	()		

Notes:

[70] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[71] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Homeostatic Model Assessment for Insulin Sensitivity (HOMA-S) at Week 32: Cohort 2 (Obesity)

End point title	Change From Baseline in Homeostatic Model Assessment for Insulin Sensitivity (HOMA-S) at Week 32: Cohort 2 (Obesity)[72]

End point description:

HOMA-S was calculated as (22.5/[FPI] * FPG) *100 and measured in terms of percentage sensitivity. Data was not collected for this endpoint as the study was terminated prior to any subject reaching Week 32.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), Week 32

Notes:

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[73]	0[74]	0[75]	0[76]
Units: Percentage sensitivity				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[73] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[74] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[75] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[76] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[77]	0[78]		
Units: Percentage sensitivity				
arithmetic mean (standard deviation)	()	()		

Notes:

[77] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

[78] - Data was not collected for this endpoint as the study was terminated prior to Week 32.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs): Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs): Cohort 1 (Type 2 Diabetes Mellitus)[79]

End point description:

An adverse event (AE) was any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study

intervention. TEAEs were any AEs that occurred on or after the first dose of treatment but before the last dose plus lag time. Safety analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to the product they actually received.

End point type	Secondary

End point timeframe:

From start of treatment up to minimum of 28 days after last dose of treatment administration (maximum up to Week 28)

Notes:

[79] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	73	72	73
Units: Subjects	35	37	50	44

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	74	73	
Units: Subjects	45	56	36	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs): Cohort 2 (Obesity)

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs): Cohort 2 (Obesity)[80]

End point description:

An AE was any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. TEAEs were any AEs that occurred on or after the first dose of treatment but before the last dose plus lag time. Safety analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to the product they actually received.

End point type	Secondary

End point timeframe:

From start of treatment up to minimum of 28 days after last dose of treatment administration (maximum up to Week 28)

Notes:

[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	66	64	65
Units: Subjects	44	54	50	56

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	64		
Units: Subjects	60	53		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Adverse Events (SAEs): Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Number of Subjects With Serious Adverse Events (SAEs): Cohort 1 (Type 2 Diabetes Mellitus)[81]

End point description:

An SAE defined was any untoward medical occurrence that, at any dose, met one or more of the following criteria: resulted in death; was life-threatening; required inpatient hospitalization or prolongation of hospitalization; resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions); resulted in congenital anomaly/birth defect; was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic; other important medical events. Safety analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to the product they actually received.

End point type	Secondary

End point timeframe:

From start of treatment up to minimum of 28 days after last dose of treatment administration (maximum up to Week 28)

Notes:

[81] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	73	72	73
Units: Subjects	1	0	3	3

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	74	73	
Units: Subjects	1	2	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Adverse Events (SAEs): Cohort 2 (Obesity)

End point title	Number of Subjects With Serious Adverse Events (SAEs): Cohort 2 (Obesity)[82]

End point description:

An SAE defined was any untoward medical occurrence that, at any dose, met one or more of the following criteria: resulted in death; was life-threatening; required inpatient hospitalization or prolongation of hospitalization; resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions); resulted in congenital anomaly/birth defect; was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic; other important medical events. Safety analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to the product they actually received.

End point type	Secondary

End point timeframe:

From start of treatment up to minimum of 28 days after last dose of treatment administration (maximum up to Week 28)

Notes:

[82] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	66	64	65
Units: Subjects	1	2	2	1

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	64		
Units: Subjects	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Adverse Events Leading to Permanent Discontinuation From Study Treatment and Study: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Number of Subjects Reporting Adverse Events Leading to Permanent Discontinuation From Study Treatment and Study: Cohort 1 (Type 2 Diabetes Mellitus)[83]

End point description:

An AE was any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs leading to permanent discontinuation from study were those with an AE record indicating the AE caused permanent discontinuation from the study. AEs leading to permanent discontinuation from study treatment were those AEs with an AE record indicating that action taken with study treatment was drug withdrawn but AE did not cause the subject to be discontinued from study. Safety Analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

From start of treatment up to minimum of 28 days after last dose of treatment administration (maximum up to Week 28)

Notes:

[83] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	73	72	73
Units: Subjects				
Discontinuations from study due to TEAEs	1	0	0	0
Discontinuations from intervention due to TEAEs	0	3	11	10

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	74	73	
Units: Subjects				
Discontinuations from study due to TEAEs	0	0	0	
Discontinuations from intervention due to TEAEs	5	17	5	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Adverse Events Leading to Permanent Discontinuation From Study Treatment and Study: Cohort 2 (Obesity)

End point title	Number of Subjects Reporting Adverse Events Leading to Permanent Discontinuation From Study Treatment and Study: Cohort 2 (Obesity)[84]

End point description:

An AE was any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs leading to permanent discontinuation from study were those with an AE record indicating the AE caused permanent discontinuation from the study. AEs leading to permanent discontinuation from study treatment were those AEs with an AE record indicating that action taken with study treatment was drug withdrawn but AE did not cause the subject to be discontinued from study. Safety Analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

From start of treatment up to minimum of 28 days after last dose of treatment administration (maximum up to Week 28)

Notes:

[84] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	66	64	65
Units: Subjects				
Discontinuations from study due to TEAEs	0	0	1	0
Discontinuations from intervention due to TEAEs	5	12	19	15

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	64		
Units: Subjects				
Discontinuations from study due to TEAEs	0	1		
Discontinuations from intervention due to TEAEs	24	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Hypoglycemic Adverse Events (HAE) According to Titration Dose: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Number of Subjects With Hypoglycemic Adverse Events (HAE) According to Titration Dose: Cohort 1 (Type 2 Diabetes Mellitus)[85]

End point description:

Glucose values monitored by glucometer. Hypoglycemia =plasma/blood glucose value of <70 mg/dL (3.9 millimoles per liter [mmol/L]). Severe HAE: Subject unable to self treat due to neurological impairment (not age) and required assistance, at least one neurological symptom of memory loss, confusion, etc. Documented blood glucose<=54 mg/dL (2.7 mmol/L). Documented symptomatic: event during which symptoms of HAE were accompanied with plasma/blood glucose <70 mg/dL and prompt resolution with food intake, SC glucagon, or IV glucose. Probable symptomatic: event during which symptoms of HAE were not accompanied by a plasma glucose determination but was presumably caused by a plasma glucose <70 mg/dL. Asymptomatic: An event not accompanied by typical symptoms of HAE, plasma/blood glucose value of <70 mg/dL. Safety Analysis set used. Here, N= total number of subjects with at least one dose of the given titration dose level after pooling of data across each titration dose.

End point type	Secondary

End point timeframe:

Up to week 28

Notes:

[85] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	PF-07081532 160mg (T2DM)	Rybelsus 14mg (T2DM)	Placebo (T2DM	PF-07081532 40 mg (T2DM)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	7	70	75	281
Units: Subjects				
Severe Hypoglycemia	0	0	0	0
Documented Symptomatic Hypoglycemia	0	1	0	2
Asymptomatic Hypoglycemia	1	2	1	1
Probable Symptomatic Hypoglycemia	0	0	0	0

End point values	PF-07081532 60mg (T2DM)	PF-07081532 80 mg (T2DM)	PF-07081532 120 mg (T2DM)	PF-07081532 140mg (T2DM)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	136	193	25	58
Units: Subjects				
Severe Hypoglycemia	0	0	0	0
Documented Symptomatic Hypoglycemia	1	0	0	0
Asymptomatic Hypoglycemia	1	1	1	1
Probable Symptomatic Hypoglycemia	0	0	0	0

End point values	PF-07081532 200mg (T2DM)	PF-07081532 260 mg (T2DM)	Rybelsus 3mg (T2DM)	Rybelsus 7mg (T2DM)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	6	73	72
Units: Subjects				

Severe Hypoglycemia	0	0	0	0
Documented Symptomatic Hypoglycemia	0	0	2	2
Asymptomatic Hypoglycemia	0	0	0	1
Probable Symptomatic Hypoglycemia	0	0	1	0

End point values	PF-07081532 20mg (T2DM)			
Subject group type	Subject analysis set			
Number of subjects analysed	364			
Units: Subjects				
Severe Hypoglycemia	1			
Documented Symptomatic Hypoglycemia	0			
Asymptomatic Hypoglycemia	0			
Probable Symptomatic Hypoglycemia	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Hypoglycemic Adverse Events According to Titration Dose: Cohort 2 (Obesity)

End point title	Number of Subjects With Hypoglycemic Adverse Events According to Titration Dose: Cohort 2 (Obesity)[86]

End point description:

Glucose values monitored by glucometer. Hypoglycemia =plasma/blood glucose value of <70 mg/dL (3.9 millimoles per liter [mmol/L]). Severe HAE: Subject unable to self treat due to neurological impairment (not age) and required assistance, at least one neurological symptom of memory loss, confusion, etc. Documented blood glucose<=54 mg/dL (2.7 mmol/L). Documented symptomatic: event during which symptoms of HAE were accompanied with plasma/blood glucose <70 mg/dL and prompt resolution with food intake, SC glucagon, or IV glucose. Probable symptomatic: event during which symptoms of HAE were not accompanied by a plasma glucose determination but was presumably caused by a plasma glucose <70 mg/dL. Asymptomatic: An event not accompanied by typical symptoms of HAE, plasma/blood glucose value of <70 mg/dL. Safety Analysis set used. Here, N= total number of subjects with at least one dose of the given titration dose level after pooling of data across each titration dose.

End point type	Secondary

End point timeframe:

Up to week 28

Notes:

[86] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 20mg (Obesity)	PF-07081532 40 mg (Obesity)	PF-07081532 60 mg (Obesity)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	64	325	310	170
Units: Subjects				
Severe Hypoglycemia	0	0	0	0
Documented Symptomatic Hypoglycemia	0	0	0	0
Asymptomatic Hypoglycemia	0	0	0	0
Probable Symptomatic Hypoglycemia	0	0	0	0

End point values	PF-07081532 100 mg (Obesity)	PF-07081532 120 mg (Obesity)	PF-07081532 160 mg (Obesity)	PF-07081532 200 mg (Obesity)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	56	43	47	121
Units: Subjects				
Severe Hypoglycemia	0	0	0	0
Documented Symptomatic Hypoglycemia	0	0	0	0
Asymptomatic Hypoglycemia	0	0	0	0
Probable Symptomatic Hypoglycemia	0	0	0	1

End point values	PF-07081532 260 mg (Obesity)	PF-07081532 80 mg (Obesity)	PF-07081532 140 mg (Obesity)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	28	220	140	
Units: Subjects				
Severe Hypoglycemia	0	0	0	
Documented Symptomatic Hypoglycemia	0	0	0	
Asymptomatic Hypoglycemia	0	0	0	
Probable Symptomatic Hypoglycemia	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Vital Sign Abnormalities: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Number of Subjects With Vital Sign Abnormalities: Cohort 1 (Type 2 Diabetes Mellitus)[87]

End point description:

Vital signs included blood pressure and pulse rate and were measured with the subjects in a seated position after at least 5 minutes of rest for the subject. Criteria for abnormalities included: Systolic Blood Pressure (millimeter of mercury [mmHg]): value more than (>) 200 and value less than (<) 90;

Diastolic blood pressure: value > 100 and < 40; Pulse rate: (beats per minute [BPM]): value < 40 and > 110. Safety analysis set (SAS) included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to the product they actually received.

End point type	Secondary

End point timeframe:

Up to Week 28

Notes:

[87] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	73	72	73
Units: Subjects				
Systolic Blood Pressure (mmHg) Value <90 mmHg	0	0	0	1
Systolic Blood Pressure (mmHg) Value >200 mmHg	0	0	0	0
Diastolic Blood Pressure (mmHg) Value <40 mmHg	0	0	0	0
Diastolic Blood Pressure (mmHg) Value >100 mmHg	0	4	2	2
Pulse Rate (bpm) Value <40 bpm	0	0	0	0
Pulse Rate (bpm) Value >110 bpm	0	1	1	0

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	74	73	
Units: Subjects				
Systolic Blood Pressure (mmHg) Value <90 mmHg	1	0	0	
Systolic Blood Pressure (mmHg) Value >200 mmHg	0	0	0	
Diastolic Blood Pressure (mmHg) Value <40 mmHg	0	0	0	
Diastolic Blood Pressure (mmHg) Value >100 mmHg	2	1	2	
Pulse Rate (bpm) Value <40 bpm	0	0	0	
Pulse Rate (bpm) Value >110 bpm	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Vital Sign Abnormalities: Cohort 2 (Obesity)

End point title	Number of Subjects With Vital Sign Abnormalities: Cohort 2 (Obesity)[88]

End point description:

Vital signs included blood pressure and pulse rate and were measured with the subjects in a seated position after at least 5 minutes of rest for the subject. Criteria for abnormalities included: Systolic blood pressure (mmHg): value > 200 and value < 90; Diastolic blood pressure: value > 100 and < 40; Pulse rate: (BPM): value < 40 and > 110. Safety analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to the product they actually received.

End point type	Secondary

End point timeframe:

Up to week 28

Notes:

[88] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	66	64	65
Units: Subjects				
Systolic Blood Pressure (mmHg) Value <90 mmHg	0	3	0	2
Systolic Blood Pressure (mmHg) Value >200 mmHg	0	0	0	0
Diastolic Blood Pressure (mmHg) Value <40 mmHg	0	0	0	0
Diastolic Blood Pressure (mmHg) Value >100 mmHg	4	4	4	0
Pulse Rate (bpm) Value <40 bpm	0	0	0	0
Pulse Rate (bpm) Value >110 bpm	0	0	0	0

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	64		
Units: Subjects				
Systolic Blood Pressure (mmHg) Value <90 mmHg	0	1		
Systolic Blood Pressure (mmHg) Value >200 mmHg	0	0		
Diastolic Blood Pressure (mmHg) Value <40 mmHg	0	0		
Diastolic Blood Pressure (mmHg) Value >100 mmHg	2	3		
Pulse Rate (bpm) Value <40 bpm	0	0		
Pulse Rate (bpm) Value >110 bpm	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinical Laboratory Abnormalities: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Number of Subjects With Clinical Laboratory Abnormalities: Cohort 1 (Type 2 Diabetes Mellitus)[89]

End point description:

Hematology: platelets (10^9/L)< 0.5*lower limit of normal (LLN);leukocytes< 0.6*LLN and >1.5*upper limit of normal (ULN); lymphocytes and neutrophils <0.8*LLN and >1.2*ULN; basophils, eosinophils, monocytes:>1.2*ULN; prothrombin time (sec)>1.1*ULN; prothrombin international normalized ratio >1.1*ULN; clinical chemistry: bilirubin (mg/dL), indirect bilirubin:>1.5*ULN; aspartate and alanine aminotransferase, gamma glutamyl transferase (U/L):>3.0*ULN; urea nitrogen and creatinine (mg/dL)>1.3*ULN;HDL cholesterol (mg/dL)<0.8*LLN; LDL (mg/dL)>1.2*ULN, Triglycerides (mg/dL):>1.3*ULN;Potassium (milliequivalents per liter) < 0.9*LLN and >1.1*ULN;calcium (mg/dL)< 0.9*LLN,Thyroxine (nanograms/dL<0.8*LLN and >1.2*ULN, HbA1C (%)>1.3*ULN; Amylase, Lipase (U/L) and Glucose -Fasting (mg/dL)>1.5*ULN; urinalysis: pH> 8; urine glucose, ketones, protein, hemoglobin, nitrite and leukocyte esterase>=1. Number of participants with abnormalities in any of the laboratory parameters is reported. SAS was used.

End point type	Secondary

End point timeframe:

Up to week 28

Notes:

[89] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	73	72	72
Units: Subjects	67	64	57	57

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	71	73	73	
Units: Subjects	61	59	64	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinical Laboratory Abnormalities: Cohort 2 (Obesity)

End point title	Number of Subjects With Clinical Laboratory Abnormalities: Cohort 2 (Obesity)[90]

End point description:

Hematology: platelets (10^9/L)< 0.5* LLN; leukocytes< 0.6*LLN and >1.5* ULN; lymphocytes and neutrophils <0.8*LLN and >1.2*ULN; basophils, eosinophils, monocytes:>1.2*ULN; prothrombin time

(sec)>1.1*ULN; prothrombin international normalized ratio >1.1*ULN; clinical chemistry: bilirubin (mg/dL), indirect bilirubin:>1.5*ULN; aspartate and alanine aminotransferase, gamma glutamyl transferase (U/L):>3.0*ULN; urea nitrogen and creatinine (mg/dL)>1.3*ULN;HDL cholesterol (mg/dL)<0.8*LLN; LDL (mg/dL)>1.2*ULN, Triglycerides (mg/dL):>1.3*ULN; Potassium (milliequivalents per liter) < 0.9*LLN and >1.1*ULN; calcium (mg/dL)< 0.9*LLN, Thyroxine (nanograms/dL<0.8*LLN and >1.2*ULN, HbA1C (%)>1.3*ULN; Amylase, Lipase (U/L) and Glucose - Fasting (mg/dL)>1.5*ULN; urinalysis: pH> 8; urine glucose, ketones, protein, hemoglobin, nitrite and leukocyte esterase>=1. Number of participants with abnormalities in any of the laboratory parameters is reported. SAS was used.

End point type	Secondary

End point timeframe:

Up to week 28

Notes:

[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	63	63	63
Units: Subjects	36	31	40	40

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	64		
Units: Subjects	48	36		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With ECG Abnormalities: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Number of Subjects With ECG Abnormalities: Cohort 1 (Type 2 Diabetes Mellitus)[91]

End point description:

Standard 12-lead ECGs were performed after the subject had rested quietly for more than 10 minutes in a supine position utilizing an ECG machine that automatically calculated the heart rate and measured PR interval, QT interval, QTcF, and QRS complex. ECG abnormalities were categorized as: PR interval (msec), Value >= 300; %Chg >= 25/50%. QRS duration (msec): Value >= 140 and %Chg >= 50%. QT interval (msec): Value > 500; QTCF interval (msec): 450 < Value <= 480, 480 < Value <= 500, Value > 500; 30 <= Change (Chg) <= 60; Chg > 60. Safety analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to the product they actually received.

End point type	Secondary

End point timeframe:

Up to week 28

Notes:

[91] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	73	72	73
Units: Subjects				
PR Interval, value>=300; n=75,73,71,73,71,73,72	1	0	0	1
PR Interval,Change>= 25/50%;n=75,73,71,73,71,73,72	0	0	0	0
QRS duration, Value≥140 n=75,73,72,73,72,74,73	1	0	0	1
QRS duration, Change >=50%; n=75,73,72,73,72,74,73	0	0	0	0
QT interval, value > 500; n=75,73,72,73,72,74,73	0	0	0	0
QTCF, 450 < Value <=480; n=75,73,72,73,72,74,73	5	7	3	5
QTCF, 480 <Value <=500; n=75,73,72,73,72,74,73	0	0	0	0
QTCF interval, Value > 500; n=75,73,72,73,72,74,73	0	0	0	0
QTCF, 30 <= Change <= 60; n=75,73,72,73,72,74,73	3	7	5	4
QTCF interval, Change > 60; n=75,73,72,73,72,74,73	0	0	0	0

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	74	73	
Units: Subjects				
PR Interval, value>=300; n=75,73,71,73,71,73,72	0	0	0	
PR Interval,Change>= 25/50%;n=75,73,71,73,71,73,72	0	0	0	
QRS duration, Value≥140 n=75,73,72,73,72,74,73	0	0	3	
QRS duration, Change >=50%; n=75,73,72,73,72,74,73	0	0	0	
QT interval, value > 500; n=75,73,72,73,72,74,73	0	0	0	
QTCF, 450 < Value <=480; n=75,73,72,73,72,74,73	5	2	5	
QTCF, 480 <Value <=500; n=75,73,72,73,72,74,73	0	0	1	
QTCF interval, Value > 500; n=75,73,72,73,72,74,73	0	0	0	
QTCF, 30 <= Change <= 60; n=75,73,72,73,72,74,73	3	10	8	

QTCF interval, Change > 60; n=75,73,72,73,72,74,73	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With ECG Abnormalities: Cohort 2 (Obesity)

End point title	Number of Subjects With ECG Abnormalities: Cohort 2 (Obesity)[92]

End point description:

Standard 12-lead ECGs were performed after the subject had rested quietly for more than 10 minutes in a supine position utilizing an ECG machine that automatically calculated the heart rate and measured PR interval, QT interval, QTcF, and QRS complex. ECG abnormalities were categorized as: PR interval msec, Value >= 300; percentage change (%) Chg >= 25/50%. QRS duration (msec): Value >= 140 and %Chg >= 50%. QT interval (msec): Value > 500; QTCF interval (msec): 450 < Value <= 480, 480 < Value <= 500, Value > 500; 30 <= change (Chg) <= 60; Chg > 60. Safety analysis set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to the product they actually received.

End point type	Secondary

End point timeframe:

Up to week 28

Notes:

[92] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	66	64	65
Units: Subjects				
PR Interval, (MSEC) value >=300	0	0	0	0
PR Interval, (MSEC) % Change >= 25/50%	0	0	0	0
QRS duration, (MSEC) value >=140	1	0	0	0
QRS duration, (MSEC) % Change >=50%	0	0	0	0
QT interval, single beat (MSEC) value > 500	0	0	0	1
QTCF interval, single beat (MSEC) 450 <Value <=480	9	3	4	2
QTCF interval, single beat (MSEC) 480 <Value <=500	0	0	0	0
QTCF interval, single beat (MSEC) Value > 500	0	0	0	0
QTCF interval, single beat (MSEC) 30 <=Change<= 60	3	8	4	4
QTCF interval, single beat (MSEC) Change > 60	0	0	0	0

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	64		
Units: Subjects				
PR Interval, (MSEC) value >=300	1	0		
PR Interval, (MSEC) % Change >= 25/50%	1	0		
QRS duration, (MSEC) value >=140	0	0		
QRS duration, (MSEC) % Change >=50%	0	0		
QT interval, single beat (MSEC) value > 500	0	0		
QTCF interval, single beat (MSEC) 450 <Value <=480	4	7		
QTCF interval, single beat (MSEC) 480 <Value <=500	0	0		
QTCF interval, single beat (MSEC) Value > 500	0	0		
QTCF interval, single beat (MSEC) 30 <=Change<= 60	4	3		
QTCF interval, single beat (MSEC) Change > 60	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects According to Columbia-Suicide Severity Rating Scale (C-SSRS) Category: Cohort 2 (Obesity) Only

End point title	Number of Subjects According to Columbia-Suicide Severity Rating Scale (C-SSRS) Category: Cohort 2 (Obesity) Only[93]

End point description:

C-SSRS is an interview-based rating scale to assess suicidal ideation and behavior and had a binary response (yes/no). C-SSRS data was mapped to C-CASA per Guidance: Suicidal Ideation and Behavior: prospective assessment of occurrence in clinical trials. A subject was said to have suicidal behavior in case of any events:1) completed suicide; 2) suicide attempt 3) preparatory acts toward imminent suicidal behavior. A subject showed suicidal ideation if they responded 'yes' to any of the 5 questions, Wish to be dead; non-specific active suicidal thoughts active suicidal ideation with any methods (Not Plan) without Intent to Act; active suicidal ideation with some intent to act, without specific plan; Active suicidal ideation with specific plan and intent. Subjects was said to exhibit Self-injurious behavior, no suicidal intent if they responded as Yes to Has subject engaged in Non-suicidal Self-Injurious Behavior. SAS was used. This endpoint was planned to be assessed in Cohort 2 only.

End point type	Secondary

End point timeframe:

Baseline (result closest prior to dosing on Day 1), anytime post-baseline (Up to Week 28)

Notes:

[93] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	66	64	65
Units: Subjects				
Baseline: <1> Completed suicide	0	0	0	0
Baseline: <2> Suicide attempt	0	0	0	0
Baseline: <3> imminent suicidal behavior	0	0	0	0
Baseline: <4> Suicidal ideation	0	0	0	0
Baseline: <7> no suicidal intent	0	0	0	0
Post-Baseline: <1> Completed suicide	0	0	0	0
Post-Baseline: <2> Suicide attempt	0	0	0	0
Post-Baseline: < 3 > imminent suicidal behavior	1	0	0	0
Post-Baseline: <4> Suicidal ideation	0	0	0	0
Post-Baseline: < 7 > no suicidal intent	1	0	0	0

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	64		
Units: Subjects				
Baseline: <1> Completed suicide	0	0		
Baseline: <2> Suicide attempt	0	0		
Baseline: <3> imminent suicidal behavior	0	0		
Baseline: <4> Suicidal ideation	0	1		
Baseline: <7> no suicidal intent	0	0		
Post-Baseline: <1> Completed suicide	0	0		
Post-Baseline: <2> Suicide attempt	0	0		
Post-Baseline: < 3 > imminent suicidal behavior	0	0		
Post-Baseline: <4> Suicidal ideation	0	1		
Post-Baseline: < 7 > no suicidal intent	0	0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Placebo-adjusted, Change From Baseline in Glycated Hemoglobin (HbA1c) at Week 16: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Placebo-adjusted, Change From Baseline in Glycated Hemoglobin (HbA1c) at Week 16: Cohort 1 (Type 2 Diabetes Mellitus)[94]

End point description:

Analysis was performed using mixed model repeated measures (MMRM) model including treatment, gender strata and time as fixed effects, baseline*time interaction, time*treatment interaction, and baseline as a covariate with time fitted as a repeated effect and participant as a random effect. Evaluable set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. Here, "Number of Subjects Analyzed" refers to subjects evaluable for this endpoint.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1) at Week 16

Notes:

[94] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	30	21	22
Units: Percentage of HbA1c				
least squares mean (standard error)	-0.07 (± 0.109)	-1.03 (± 0.106)	-1.37 (± 0.112)	-1.44 (± 0.111)

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	21	24	
Units: Percentage of HbA1c				
least squares mean (standard error)	-1.34 (± 0.110)	-1.36 (± 0.114)	-0.94 (± 0.109)	

Statistical analyses

Statistical analysis title	Placebo (T2DM) and PF-07081532 20mg (T2DM)
Comparison groups	Placebo (T2DM) v PF-07081532 20mg (T2DM)
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-0.95
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.2
upper limit	-0.7

Statistical analysis title	Placebo (T2DM) and PF-07081532 40mg (T2DM)
Comparison groups	Placebo (T2DM) v PF-07081532 40mg (T2DM)
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-1.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.55
upper limit	-1.04

Statistical analysis title	Placebo (T2DM) and PF-07081532 260mg (T2DM)
Comparison groups	Placebo (T2DM) v PF-07081532 260mg (T2DM)
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-1.29
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.55
upper limit	-1.03

Statistical analysis title	Placebo (T2DM) and PF-07081532 160mg (T2DM)
Comparison groups	Placebo (T2DM) v PF-07081532 160mg (T2DM)
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-1.26

Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.52
upper limit	-1.01

Statistical analysis title	Placebo (T2DM) and Rybelsus 14 mg (Obesity)
Comparison groups	Placebo (T2DM) v Rybelsus 14mg (T2DM)
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-0.86
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.12
upper limit	-0.61

Statistical analysis title	Placebo (T2DM) and PF-07081532 80mg (T2DM)
Comparison groups	Placebo (T2DM) v PF-07081532 80mg (T2DM)
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-1.37
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.62
upper limit	-1.11

Other pre-specified: Placebo-adjusted, Percent Change From Baseline in Body Weight at Week 20: Cohort 2 (Obesity)

End point title	Placebo-adjusted, Percent Change From Baseline in Body Weight at Week 20: Cohort 2 (Obesity)[95]

End point description:

Body weight was measured using a calibrated weighing scale. Analysis was performed using MMRM model including treatment, gender strata and time as fixed effects, baseline*time interaction, time*treatment interaction, and baseline as a covariate with time fitted as a repeated effect and participant as a random effect. Evaluable set included all subjects randomly assigned to study

intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. Here, "Number of Subjects Analyzed" refers to subjects evaluable for this endpoint.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1), at Week 20

Notes:

[95] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	44	37	38
Units: Percent change				
least squares mean (standard error)	-1.84 (± 0.612)	-4.28 (± 0.623)	-6.21 (± 0.654)	-7.47 (± 0.628)

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	28		
Units: Percent change				
least squares mean (standard error)	-6.88 (± 0.638)	-7.26 (± 0.664)		

Statistical analyses

Statistical analysis title	Placebo (Obesity) and PF-07081532 80mg (Obesity)
Comparison groups	Placebo (Obesity) v PF-07081532 80mg (Obesity)
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0055
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-2.44
Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.88
upper limit	-1

Statistical analysis title	Placebo (Obesity) and PF-07081532 140mg (Obesity)
Comparison groups	Placebo (Obesity) v PF-07081532 140mg (Obesity)
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-4.37
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.84
upper limit	-2.89

Statistical analysis title	Placebo (Obesity), PF-07081532 200mg (5 steps)
Comparison groups	Placebo (Obesity) v PF-07081532 200mg (Obesity,5 steps)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-5.63
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.07
upper limit	-4.18

Statistical analysis title	Placebo (Obesity) & PF-07081532 200mg (4 steps)
Comparison groups	Placebo (Obesity) v PF-07081532 200mg (Obesity,4 steps)
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-5.04

Confidence interval	
level	90 %
sides	2-sided
lower limit	-6.5
upper limit	-3.58

Statistical analysis title	Placebo (Obesity) and PF-07081532 260mg (Obesity)
Comparison groups	Placebo (Obesity) v PF-07081532 260mg (Obesity)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-5.42
Confidence interval	
level	90 %
sides	2-sided
lower limit	-6.91
upper limit	-3.93

Other pre-specified: Change From Baseline in Fasting Plasma Glucose (FPG) at Week 16: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 16: Cohort 1 (Type 2 Diabetes Mellitus)[96]

End point description:

Evaluable set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. Here, "Number of Subjects Analyzed" refers to subjects evaluable for this endpoint.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1), at Week 16

Notes:

[96] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	30	21	22
Units: Milligrams per deciliter				
arithmetic mean (standard deviation)	160.70 (± 39.595)	135.59 (± 31.746)	127.00 (± 35.928)	132.19 (± 31.541)

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	21	24	
Units: Milligrams per deciliter				
arithmetic mean (standard deviation)	127.65 (± 28.839)	125.07 (± 46.924)	130.06 (± 28.120)	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percent Change From Baseline in Body Weight at Week 16: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Percent Change From Baseline in Body Weight at Week 16: Cohort 1 (Type 2 Diabetes Mellitus)[97]

End point description:

Body weight was measured using a calibrated weighing scale. Evaluable set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. Here, "Number of Subjects Analyzed" refers to subjects evaluable for this endpoint.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1), at Week 16

Notes:

[97] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	PF-07081532 20mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 80mg (T2DM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	32	30	28
Units: Percent change				
arithmetic mean (standard deviation)	93.164 (± 22.0659)	86.251 (± 17.3464)	91.556 (± 23.4071)	92.979 (± 24.5045)

End point values	PF-07081532 160mg (T2DM)	PF-07081532 260mg (T2DM)	Rybelsus 14mg (T2DM)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	30	27	
Units: Percent change				
arithmetic mean (standard deviation)	85.564 (± 17.9582)	87.658 (± 21.6950)	91.799 (± 20.4605)	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Absolute Change From Baseline in Waist Circumference at Week 12 and 24: Cohort 2 (Obesity)

End point title	Absolute Change From Baseline in Waist Circumference at Week 12 and 24: Cohort 2 (Obesity)[98]

End point description:

Waist circumference was measured at midpoint, between lower margin of last palpable rib and top of iliac crest (approximately 1 inch [2.54 cm] above the navel). It was measured by using an anthropometric tape (stretch-resistant). Evaluable set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. Here, "Number of Subjects Analyzed" refers to subjects evaluable for this endpoint. N=subjects evaluable for specified timepoints.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1), at Week 12, 24

Notes:

[98] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	53	49	56
Units: Cm				
arithmetic mean (standard deviation)				
Week 12; n=57,53,49,56,53,50	-2.702 (± 4.1726)	-2.574 (± 5.0872)	-3.017 (± 5.9117)	-3.559 (± 6.5122)
Week 24; n=12,12,11,9,7,4	-4.233 (± 5.3953)	-5.147 (± 4.1807)	-6.314 (± 10.2170)	-2.722 (± 7.6706)

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	50		
Units: Cm				
arithmetic mean (standard deviation)				
Week 12; n=57,53,49,56,53,50	-2.191 (± 5.2942)	-1.079 (± 4.6710)		
Week 24; n=12,12,11,9,7,4	-10.297 (± 7.7652)	-6.450 (± 4.2123)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Placebo-adjusted, Change From Baseline in Percentage of HbA1C in the Rybelsus arm Versus Placebo arm at Week 16: Cohort 1 (Type 2 Diabetes Mellitus)

End point title	Placebo-adjusted, Change From Baseline in Percentage of HbA1C in the Rybelsus arm Versus Placebo arm at Week 16: Cohort 1 (Type 2 Diabetes Mellitus)[99]

End point description:

Analysis was performed using MMRM model including treatment, gender strata and time as fixed effects, baseline*time interaction, time*treatment interaction, and baseline as a covariate with time fitted as a repeated effect and participant as a random effect. Evaluable set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. This endpoint was planned to be analyzed only for rybelsus arm and placebo arm as pre-specified in the protocol.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1), at Week 16

Notes:

[99] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (T2DM)	Rybelsus 14mg (T2DM)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	24		
Units: Percentage of HbA1C				
least squares mean (standard error)	-0.07 (± 0.109)	-0.94 (± 0.109)		

Statistical analyses

Statistical analysis title	Rybelsus 14 mg (T2DM) and Placebo (T2DM)
Comparison groups	Rybelsus 14mg (T2DM) v Placebo (T2DM)
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference
Point estimate	-0.86
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.12
upper limit	-0.61

Other pre-specified: Absolute Change From Baseline in Waist-to-hip Ratio at Week 12 and Week 24: Cohort 2 (Obesity)

End point title	Absolute Change From Baseline in Waist-to-hip Ratio at Week

	12 and Week 24: Cohort 2 (Obesity)[100]

End point description:

The hip circumference was defined as the circumference around the widest portion of the buttocks. Waist circumference was measured at midpoint, between lower margin of last palpable rib and top of iliac crest (approximately 1 inch [2.54 cm] above the navel). The measurements were performed using an anthropometric tape (stretch-resistant). Evaluable set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. Here, "Number of Subjects Analyzed" refers to subjects evaluable for this endpoint.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1), at week 12, 24

Notes:

[100] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	53	49	56
Units: Ratio				
arithmetic mean (standard deviation)				
Week 12	-0.013 (± 0.0374)	-0.002 (± 0.0459)	-0.006 (± 0.0578)	-0.010 (± 0.0683)
Week 24	-0.023 (± 0.0419)	-0.017 (± 0.0250)	-0.032 (± 0.0588)	0.018 (± 0.0563)

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	50		
Units: Ratio				
arithmetic mean (standard deviation)				
Week 12	-0.002 (± 0.0423)	0.015 (± 0.0557)		
Week 24	-0.009 (± 0.0498)	-0.037 (± 0.0574)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline in Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) at Week 16: Cohort 2 (Obesity)

End point title	Change From Baseline in Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) at Week 16: Cohort 2 (Obesity)[101]

End point description:

HOMA-IR was calculated as: ([FPI]*(FPG)/405 in terms of Mg/dL* (milliunits per liter). Evaluable set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. Here, "Number of Subjects Analyzed" refers to subjects evaluable for this endpoint.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1), Week 16

Notes:

[101] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	48	42	46
Units: Mg/dL* (milliunits per liter)				
arithmetic mean (standard deviation)	0.630 (± 2.1753)	0.185 (± 2.0579)	-0.121 (± 4.7540)	0.984 (± 3.9090)

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	39		
Units: Mg/dL* (milliunits per liter)				
arithmetic mean (standard deviation)	-1.172 (± 2.7360)	-0.210 (± 1.1373)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline in Homeostatic Model Assessment for Insulin Sensitivity (HOMA-S) at Week 16: Cohort 2 (Obesity)

End point title	Change From Baseline in Homeostatic Model Assessment for Insulin Sensitivity (HOMA-S) at Week 16: Cohort 2 (Obesity)[102]

End point description:

HOMA-S was calculated as (22.5/[FPI]*FPG)) *100 and measured in terms of percentage sensitivity. Evaluable set included all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. Subjects were analyzed according to randomized intervention. Here, "Number of Subjects Analyzed" refers to subjects evaluable for this endpoint.

End point type	Other pre-specified

End point timeframe:

Baseline (Baseline is defined as the result closest prior to dosing at Visit 3 (Day 1), Week 16

Notes:

[102] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistical Analysis was not planned for this endpoint

End point values	Placebo (Obesity)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)	PF-07081532 200mg (Obesity,5 steps)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	48	42	46
Units: Percentage sensitivity				
arithmetic mean (standard deviation)	-2.419 (± 51.8526)	1.594 (± 24.1848)	7.807 (± 26.5041)	-7.085 (± 21.6406)

End point values	PF-07081532 200mg (Obesity,4 steps)	PF-07081532 260mg (Obesity)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	39		
Units: Percentage sensitivity				
arithmetic mean (standard deviation)	3.497 (± 68.2570)	-2.045 (± 28.8973)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Part 1 and 2: From start of treatment up to minimum of 28 days after last dose of treatment administration (maximum up to Week 28)

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE. What is presented are distinct events. An event may be categorized as serious in 1 subject and non-serious in other subject, or a subject may have experienced both SAE and non-SAE. Safety analysis set was used.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v26.0

Reporting groups

Reporting group title	PF-07081532 80mg (T2DM)

Reporting group description:

Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks each followed by PF-07081532 80 mg QD orally.

Reporting group title	PF-07081532 40mg (T2DM)

Reporting group description:

Subjects with T2DM inadequately controlled with metformin were administered PF-07081532 20 mg QD orally for 4 weeks followed by PF-07081532 40 mg QD orally.

Reporting group title	PF-07081532 20mg (T2DM)

Reporting group description:

Subjects with T2DM inadequately controlled with metformin were administered PF-07081532 20 mg QD orally.

Reporting group title	Placebo (T2DM)

Reporting group description:

Subjects with T2DM inadequately controlled with metformin were administered PF-07081532-matching placebo QD orally.

Reporting group title	PF-07081532 80mg (Obesity)

Reporting group description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD orally for 4 weeks each followed by PF-07081532 80 mg QD orally.

Reporting group title	PF-07081532 140mg (Obesity)

Reporting group description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 80 mg QD,120 mg QD orally for 4 weeks each followed by PF-07081532 140 mg QD orally.

Reporting group title	PF-07081532 200mg (Obesity,5 steps)

Reporting group description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 60 mg QD, 100 mg QD,160 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.

Reporting group title	PF-07081532 200mg (Obesity,4 steps)

Reporting group description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 80 mg QD, 140 mg QD orally for 4 weeks each followed by PF-07081532 200 mg QD orally.

Reporting group title	Placebo (Obesity)

Reporting group description:

Subjects with obesity were administered a single dose of PF-07081532-matching placebo QD orally.

Reporting group title	PF-07081532 260mg (Obesity)

Reporting group description:

Subjects with obesity were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD and 80

mg QD, 140 mg QD, 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.

Reporting group title	PF-07081532 260mg (T2DM)

Reporting group description:

Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD, 40 mg QD, 80 mg QD, 140 mg QD and 200 mg QD orally for 4 weeks each followed by PF-07081532 260 mg QD orally.

Reporting group title	PF-07081532 160mg (T2DM)

Reporting group description:

Subjects with T2DM inadequately controlled with metformin were administered titrating doses of PF-07081532 20 mg QD 40 mg QD, 60 mg QD, 80 mg QD and 120 mg QD orally for 4 weeks each followed by PF-07081532 160 mg QD orally.

Reporting group title	Rybelsus 14mg (T2DM)

Reporting group description:

Subjects with T2DM inadequately controlled with metformin were administered titrating doses of Rybelsus 3 mg QD and 7 mg QD each for 4 weeks followed by 14 mg QD.

Serious adverse events	PF-07081532 80mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 20mg (T2DM)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 73 (4.11%)	3 / 72 (4.17%)	0 / 73 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Carcinoid tumour			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Allergic respiratory symptom			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

COVID-19 pneumonia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo (T2DM)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 75 (1.33%)	2 / 66 (3.03%)	2 / 64 (3.13%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			

subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Carcinoid tumour			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 75 (1.33%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Allergic respiratory symptom			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-07081532 200mg (Obesity,5 steps)	PF-07081532 200mg (Obesity,4 steps)	Placebo (Obesity)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 65 (1.54%)	2 / 66 (3.03%)	1 / 64 (1.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 65 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 65 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Carcinoid tumour			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myocardial ischaemia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hypertransaminasaemia			

subjects affected / exposed	0 / 65 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Allergic respiratory symptom			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	1 / 65 (1.54%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-07081532 260mg (Obesity)	PF-07081532 260mg (T2DM)	PF-07081532 160mg (T2DM)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 64 (3.13%)	2 / 74 (2.70%)	1 / 72 (1.39%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 64 (0.00%)	1 / 74 (1.35%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Carcinoid tumour			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 64 (0.00%)	1 / 74 (1.35%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Allergic respiratory symptom			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Rybelsus 14mg (T2DM)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 73 (1.37%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver function test abnormal			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver function test increased			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Carcinoid tumour			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal			

conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Allergic respiratory symptom			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epistaxis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19 pneumonia			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	PF-07081532 80mg (T2DM)	PF-07081532 40mg (T2DM)	PF-07081532 20mg (T2DM)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	37 / 73 (50.68%)	46 / 72 (63.89%)	31 / 73 (42.47%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	1 / 73 (1.37%)	4 / 72 (5.56%)	0 / 73 (0.00%)
occurrences (all)	1	5	0
Asthenia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	0	2
Oropharyngeal pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Depressed mood			

subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 73 (2.74%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	2	1	0
Lipase increased			
subjects affected / exposed	1 / 73 (1.37%)	4 / 72 (5.56%)	3 / 73 (4.11%)
occurrences (all)	1	5	3
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 73 (2.74%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	2	1	0
Liver function test increased			
subjects affected / exposed	2 / 73 (2.74%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	2	1	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 73 (1.37%)	2 / 72 (2.78%)	0 / 73 (0.00%)
occurrences (all)	1	2	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	0	3
Palpitations			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Dizziness			
subjects affected / exposed	1 / 73 (1.37%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	2	1	0
Headache			
subjects affected / exposed	2 / 73 (2.74%)	5 / 72 (6.94%)	2 / 73 (2.74%)
occurrences (all)	3	5	2
Dysgeusia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	0	2
Migraine			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 73 (0.00%)	2 / 72 (2.78%)	0 / 73 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	2 / 73 (2.74%)	5 / 72 (6.94%)	1 / 73 (1.37%)
occurrences (all)	2	6	1
Abdominal pain upper			
subjects affected / exposed	1 / 73 (1.37%)	5 / 72 (6.94%)	3 / 73 (4.11%)
occurrences (all)	1	6	4
Abdominal pain			
subjects affected / exposed	1 / 73 (1.37%)	5 / 72 (6.94%)	0 / 73 (0.00%)
occurrences (all)	1	7	0
Constipation			
subjects affected / exposed	3 / 73 (4.11%)	7 / 72 (9.72%)	2 / 73 (2.74%)
occurrences (all)	3	7	2
Eructation			

subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	4 / 73 (5.48%)	2 / 72 (2.78%)	3 / 73 (4.11%)
occurrences (all)	5	2	3
Diarrhoea			
subjects affected / exposed	8 / 73 (10.96%)	9 / 72 (12.50%)	8 / 73 (10.96%)
occurrences (all)	8	9	9
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 73 (4.11%)	2 / 72 (2.78%)	0 / 73 (0.00%)
occurrences (all)	3	2	0
Nausea			
subjects affected / exposed	21 / 73 (28.77%)	17 / 72 (23.61%)	11 / 73 (15.07%)
occurrences (all)	31	21	14
Vomiting			
subjects affected / exposed	11 / 73 (15.07%)	6 / 72 (8.33%)	1 / 73 (1.37%)
occurrences (all)	14	8	1
Flatulence			
subjects affected / exposed	1 / 73 (1.37%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	1	1	0
Abdominal discomfort			
subjects affected / exposed	1 / 73 (1.37%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	1	1	0
Dry mouth			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 73 (1.37%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	1	1	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	1 / 73 (1.37%)	3 / 72 (4.17%)	0 / 73 (0.00%)
occurrences (all)	1	3	0
Cholelithiasis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 73 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 73 (0.00%)	3 / 72 (4.17%)	0 / 73 (0.00%)
occurrences (all)	0	3	0
Microalbuminuria			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	0	2
Haematuria			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 73 (1.37%)	1 / 72 (1.39%)	2 / 73 (2.74%)
occurrences (all)	1	1	2
Muscle spasms			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	2 / 73 (2.74%)
occurrences (all)	1	0	2
Musculoskeletal chest pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0

Osteoarthritis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	2 / 73 (2.74%)
occurrences (all)	1	0	2
Nasopharyngitis			
subjects affected / exposed	2 / 73 (2.74%)	3 / 72 (4.17%)	0 / 73 (0.00%)
occurrences (all)	2	3	0
Urinary tract infection			
subjects affected / exposed	1 / 73 (1.37%)	4 / 72 (5.56%)	1 / 73 (1.37%)
occurrences (all)	2	5	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	1 / 73 (1.37%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	0	2
Cellulitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	1	0	0
Ear infection			

subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 73 (4.11%)	5 / 72 (6.94%)	1 / 73 (1.37%)
occurrences (all)	3	5	1
Hyperglycaemia			
subjects affected / exposed	1 / 73 (1.37%)	1 / 72 (1.39%)	1 / 73 (1.37%)
occurrences (all)	1	1	1
Hypokalaemia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo (T2DM)	PF-07081532 80mg (Obesity)	PF-07081532 140mg (Obesity)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 75 (30.67%)	50 / 66 (75.76%)	48 / 64 (75.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 75 (0.00%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Flushing			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 75 (0.00%)	7 / 66 (10.61%)	5 / 64 (7.81%)
occurrences (all)	0	11	6

Asthenia			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Chest discomfort			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Early satiety			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Pain			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	1 / 64 (1.56%)
occurrences (all)	0	1	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 75 (0.00%)	3 / 66 (4.55%)	0 / 64 (0.00%)
occurrences (all)	0	3	0
Insomnia			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	2 / 64 (3.13%)
occurrences (all)	0	1	2
Lipase increased			
subjects affected / exposed	0 / 75 (0.00%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	2 / 64 (3.13%)
occurrences (all)	0	1	2
Liver function test increased			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	1 / 64 (1.56%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 75 (2.67%)	4 / 66 (6.06%)	2 / 64 (3.13%)
occurrences (all)	2	5	2

Headache			
subjects affected / exposed	0 / 75 (0.00%)	7 / 66 (10.61%)	4 / 64 (6.25%)
occurrences (all)	0	9	4
Dysgeusia			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	1 / 64 (1.56%)
occurrences (all)	0	1	1
Head discomfort			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 75 (0.00%)	2 / 66 (3.03%)	3 / 64 (4.69%)
occurrences (all)	0	2	3
Abdominal pain upper			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	4 / 64 (6.25%)
occurrences (all)	0	1	4
Abdominal pain			
subjects affected / exposed	0 / 75 (0.00%)	3 / 66 (4.55%)	6 / 64 (9.38%)
occurrences (all)	0	3	7
Constipation			
subjects affected / exposed	1 / 75 (1.33%)	14 / 66 (21.21%)	15 / 64 (23.44%)
occurrences (all)	1	15	17
Eructation			
subjects affected / exposed	0 / 75 (0.00%)	3 / 66 (4.55%)	0 / 64 (0.00%)
occurrences (all)	0	4	0
Dyspepsia			

subjects affected / exposed	1 / 75 (1.33%)	6 / 66 (9.09%)	4 / 64 (6.25%)
occurrences (all)	1	6	5
Diarrhoea			
subjects affected / exposed	1 / 75 (1.33%)	10 / 66 (15.15%)	10 / 64 (15.63%)
occurrences (all)	1	15	13
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 75 (0.00%)	10 / 66 (15.15%)	6 / 64 (9.38%)
occurrences (all)	0	15	7
Nausea			
subjects affected / exposed	3 / 75 (4.00%)	34 / 66 (51.52%)	30 / 64 (46.88%)
occurrences (all)	4	51	41
Vomiting			
subjects affected / exposed	1 / 75 (1.33%)	7 / 66 (10.61%)	10 / 64 (15.63%)
occurrences (all)	1	8	13
Flatulence			
subjects affected / exposed	1 / 75 (1.33%)	1 / 66 (1.52%)	1 / 64 (1.56%)
occurrences (all)	1	5	1
Abdominal discomfort			
subjects affected / exposed	0 / 75 (0.00%)	3 / 66 (4.55%)	1 / 64 (1.56%)
occurrences (all)	0	3	2
Dry mouth			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	2 / 75 (2.67%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	2 / 64 (3.13%)
occurrences (all)	0	1	3
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 75 (1.33%)	2 / 66 (3.03%)	1 / 64 (1.56%)
occurrences (all)	1	2	1
Muscle spasms			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	1 / 64 (1.56%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Arthralgia			
subjects affected / exposed	0 / 75 (0.00%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Osteoarthritis			

subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 75 (0.00%)	3 / 66 (4.55%)	2 / 64 (3.13%)
occurrences (all)	0	4	2
Nasopharyngitis			
subjects affected / exposed	1 / 75 (1.33%)	5 / 66 (7.58%)	2 / 64 (3.13%)
occurrences (all)	1	6	2
Urinary tract infection			
subjects affected / exposed	1 / 75 (1.33%)	2 / 66 (3.03%)	2 / 64 (3.13%)
occurrences (all)	2	2	2
Upper respiratory tract infection			
subjects affected / exposed	2 / 75 (2.67%)	2 / 66 (3.03%)	1 / 64 (1.56%)
occurrences (all)	2	2	1
Sinusitis			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	3 / 64 (4.69%)
occurrences (all)	0	0	3
Bronchitis			
subjects affected / exposed	1 / 75 (1.33%)	4 / 66 (6.06%)	1 / 64 (1.56%)
occurrences (all)	1	4	1
Cellulitis			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Gastroenteritis			
subjects affected / exposed	0 / 75 (0.00%)	1 / 66 (1.52%)	1 / 64 (1.56%)
occurrences (all)	0	1	1
Ear infection			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0

Viral infection			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	3
Pharyngitis			
subjects affected / exposed	2 / 75 (2.67%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 75 (1.33%)	5 / 66 (7.58%)	7 / 64 (10.94%)
occurrences (all)	1	5	7
Hyperglycaemia			
subjects affected / exposed	6 / 75 (8.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	6	0	0
Hypokalaemia			
subjects affected / exposed	0 / 75 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PF-07081532 200mg (Obesity,5 steps)	PF-07081532 200mg (Obesity,4 steps)	Placebo (Obesity)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	55 / 65 (84.62%)	59 / 66 (89.39%)	42 / 64 (65.63%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 65 (1.54%)	2 / 66 (3.03%)	4 / 64 (6.25%)
occurrences (all)	1	2	4
Flushing			
subjects affected / exposed	0 / 65 (0.00%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Hypotension			
subjects affected / exposed	0 / 65 (0.00%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 65 (9.23%)	5 / 66 (7.58%)	5 / 64 (7.81%)
occurrences (all)	9	8	5
Asthenia			

subjects affected / exposed	0 / 65 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Early satiety			
subjects affected / exposed	0 / 65 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	1 / 65 (1.54%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	1	0	2
Cough			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 65 (1.54%)	1 / 66 (1.52%)	3 / 64 (4.69%)
occurrences (all)	1	1	3
Sinus congestion			
subjects affected / exposed	2 / 65 (3.08%)	1 / 66 (1.52%)	1 / 64 (1.56%)
occurrences (all)	2	1	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	3 / 65 (4.62%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	3	3	0
Depressed mood			
subjects affected / exposed	1 / 65 (1.54%)	1 / 66 (1.52%)	2 / 64 (3.13%)
occurrences (all)	1	1	2
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	1 / 65 (1.54%)	4 / 66 (6.06%)	2 / 64 (3.13%)
occurrences (all)	1	4	2
Lipase increased			
subjects affected / exposed	0 / 65 (0.00%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 65 (0.00%)	3 / 66 (4.55%)	1 / 64 (1.56%)
occurrences (all)	0	3	1
Liver function test increased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 65 (0.00%)	2 / 66 (3.03%)	1 / 64 (1.56%)
occurrences (all)	0	2	1
Ligament sprain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 65 (1.54%)	4 / 66 (6.06%)	3 / 64 (4.69%)
occurrences (all)	1	6	3

Headache			
subjects affected / exposed	7 / 65 (10.77%)	9 / 66 (13.64%)	5 / 64 (7.81%)
occurrences (all)	11	21	5
Dysgeusia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	2 / 65 (3.08%)	1 / 66 (1.52%)	1 / 64 (1.56%)
occurrences (all)	2	1	1
Head discomfort			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 65 (1.54%)	3 / 66 (4.55%)	4 / 64 (6.25%)
occurrences (all)	2	6	5
Abdominal pain upper			
subjects affected / exposed	6 / 65 (9.23%)	3 / 66 (4.55%)	1 / 64 (1.56%)
occurrences (all)	7	4	1
Abdominal pain			
subjects affected / exposed	2 / 65 (3.08%)	10 / 66 (15.15%)	4 / 64 (6.25%)
occurrences (all)	3	14	6
Constipation			
subjects affected / exposed	15 / 65 (23.08%)	23 / 66 (34.85%)	5 / 64 (7.81%)
occurrences (all)	20	31	5
Eructation			
subjects affected / exposed	2 / 65 (3.08%)	4 / 66 (6.06%)	0 / 64 (0.00%)
occurrences (all)	3	9	0
Dyspepsia			

subjects affected / exposed	6 / 65 (9.23%)	9 / 66 (13.64%)	2 / 64 (3.13%)
occurrences (all)	7	13	2
Diarrhoea			
subjects affected / exposed	16 / 65 (24.62%)	17 / 66 (25.76%)	12 / 64 (18.75%)
occurrences (all)	23	36	17
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 65 (7.69%)	13 / 66 (19.70%)	1 / 64 (1.56%)
occurrences (all)	5	13	1
Nausea			
subjects affected / exposed	38 / 65 (58.46%)	40 / 66 (60.61%)	8 / 64 (12.50%)
occurrences (all)	56	84	9
Vomiting			
subjects affected / exposed	21 / 65 (32.31%)	19 / 66 (28.79%)	1 / 64 (1.56%)
occurrences (all)	41	30	1
Flatulence			
subjects affected / exposed	1 / 65 (1.54%)	3 / 66 (4.55%)	2 / 64 (3.13%)
occurrences (all)	1	3	2
Abdominal discomfort			
subjects affected / exposed	3 / 65 (4.62%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	3	4	0
Dry mouth			
subjects affected / exposed	2 / 65 (3.08%)	1 / 66 (1.52%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Gastritis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	2 / 65 (3.08%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 65 (0.00%)	2 / 66 (3.03%)	1 / 64 (1.56%)
occurrences (all)	0	3	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 65 (4.62%)	4 / 66 (6.06%)	2 / 64 (3.13%)
occurrences (all)	3	4	2
Muscle spasms			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 65 (1.54%)	3 / 66 (4.55%)	1 / 64 (1.56%)
occurrences (all)	1	3	1
Myalgia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	1 / 64 (1.56%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	2 / 65 (3.08%)	3 / 66 (4.55%)	0 / 64 (0.00%)
occurrences (all)	2	3	0
Osteoarthritis			

subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 65 (1.54%)	2 / 66 (3.03%)	5 / 64 (7.81%)
occurrences (all)	1	2	5
Nasopharyngitis			
subjects affected / exposed	4 / 65 (6.15%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	5	2	0
Urinary tract infection			
subjects affected / exposed	6 / 65 (9.23%)	5 / 66 (7.58%)	2 / 64 (3.13%)
occurrences (all)	7	5	3
Upper respiratory tract infection			
subjects affected / exposed	4 / 65 (6.15%)	5 / 66 (7.58%)	3 / 64 (4.69%)
occurrences (all)	4	5	3
Sinusitis			
subjects affected / exposed	1 / 65 (1.54%)	2 / 66 (3.03%)	4 / 64 (6.25%)
occurrences (all)	1	2	4
Bronchitis			
subjects affected / exposed	3 / 65 (4.62%)	0 / 66 (0.00%)	1 / 64 (1.56%)
occurrences (all)	3	0	1
Cellulitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Cystitis			
subjects affected / exposed	0 / 65 (0.00%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 65 (0.00%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	3 / 65 (4.62%)	2 / 66 (3.03%)	2 / 64 (3.13%)
occurrences (all)	4	2	2
Ear infection			
subjects affected / exposed	1 / 65 (1.54%)	2 / 66 (3.03%)	0 / 64 (0.00%)
occurrences (all)	1	2	0

Viral infection			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 65 (4.62%)	8 / 66 (12.12%)	5 / 64 (7.81%)
occurrences (all)	3	9	6
Hyperglycaemia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 66 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PF-07081532 260mg (Obesity)	PF-07081532 260mg (T2DM)	PF-07081532 160mg (T2DM)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 64 (82.81%)	51 / 74 (68.92%)	41 / 72 (56.94%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Flushing			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	2 / 72 (2.78%)
occurrences (all)	1	0	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 64 (7.81%)	2 / 74 (2.70%)	2 / 72 (2.78%)
occurrences (all)	5	2	3
Asthenia			

subjects affected / exposed	2 / 64 (3.13%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Chest discomfort			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Early satiety			
subjects affected / exposed	2 / 64 (3.13%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Pain			
subjects affected / exposed	2 / 64 (3.13%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 64 (3.13%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Depressed mood			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	1 / 64 (1.56%)	2 / 74 (2.70%)	1 / 72 (1.39%)
occurrences (all)	1	2	1
Lipase increased			
subjects affected / exposed	2 / 64 (3.13%)	3 / 74 (4.05%)	0 / 72 (0.00%)
occurrences (all)	2	3	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Liver function test increased			
subjects affected / exposed	0 / 64 (0.00%)	1 / 74 (1.35%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Hepatic enzyme increased			
subjects affected / exposed	0 / 64 (0.00%)	1 / 74 (1.35%)	2 / 72 (2.78%)
occurrences (all)	0	1	2
Amylase increased			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 64 (6.25%)	7 / 74 (9.46%)	2 / 72 (2.78%)
occurrences (all)	4	8	2

Headache			
subjects affected / exposed	5 / 64 (7.81%)	1 / 74 (1.35%)	1 / 72 (1.39%)
occurrences (all)	8	1	1
Dysgeusia			
subjects affected / exposed	2 / 64 (3.13%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Migraine			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 64 (3.13%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 64 (3.13%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	4 / 64 (6.25%)	1 / 74 (1.35%)	2 / 72 (2.78%)
occurrences (all)	5	1	2
Abdominal pain upper			
subjects affected / exposed	3 / 64 (4.69%)	1 / 74 (1.35%)	1 / 72 (1.39%)
occurrences (all)	4	1	1
Abdominal pain			
subjects affected / exposed	4 / 64 (6.25%)	2 / 74 (2.70%)	1 / 72 (1.39%)
occurrences (all)	8	2	1
Constipation			
subjects affected / exposed	17 / 64 (26.56%)	6 / 74 (8.11%)	4 / 72 (5.56%)
occurrences (all)	19	6	4
Eructation			
subjects affected / exposed	5 / 64 (7.81%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	11	0	0
Dyspepsia			

subjects affected / exposed	4 / 64 (6.25%)	3 / 74 (4.05%)	4 / 72 (5.56%)
occurrences (all)	5	3	4
Diarrhoea			
subjects affected / exposed	17 / 64 (26.56%)	8 / 74 (10.81%)	4 / 72 (5.56%)
occurrences (all)	33	10	4
Gastrooesophageal reflux disease			
subjects affected / exposed	6 / 64 (9.38%)	3 / 74 (4.05%)	4 / 72 (5.56%)
occurrences (all)	7	3	4
Nausea			
subjects affected / exposed	32 / 64 (50.00%)	19 / 74 (25.68%)	14 / 72 (19.44%)
occurrences (all)	49	22	17
Vomiting			
subjects affected / exposed	22 / 64 (34.38%)	11 / 74 (14.86%)	6 / 72 (8.33%)
occurrences (all)	38	16	11
Flatulence			
subjects affected / exposed	4 / 64 (6.25%)	4 / 74 (5.41%)	0 / 72 (0.00%)
occurrences (all)	10	4	0
Abdominal discomfort			
subjects affected / exposed	3 / 64 (4.69%)	6 / 74 (8.11%)	5 / 72 (6.94%)
occurrences (all)	3	7	5
Dry mouth			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 64 (0.00%)	3 / 74 (4.05%)	0 / 72 (0.00%)
occurrences (all)	0	3	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 64 (0.00%)	4 / 74 (5.41%)	2 / 72 (2.78%)
occurrences (all)	0	4	2
Cholelithiasis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 64 (1.56%)	1 / 74 (1.35%)	0 / 72 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 64 (4.69%)	1 / 74 (1.35%)	0 / 72 (0.00%)
occurrences (all)	3	1	0
Muscle spasms			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 64 (0.00%)	2 / 74 (2.70%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Pain in extremity			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	3
Myalgia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	5 / 64 (7.81%)	2 / 74 (2.70%)	1 / 72 (1.39%)
occurrences (all)	5	2	1
Nasopharyngitis			
subjects affected / exposed	4 / 64 (6.25%)	2 / 74 (2.70%)	1 / 72 (1.39%)
occurrences (all)	5	2	1
Urinary tract infection			
subjects affected / exposed	3 / 64 (4.69%)	6 / 74 (8.11%)	0 / 72 (0.00%)
occurrences (all)	5	7	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 64 (0.00%)	2 / 74 (2.70%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Cellulitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Ear infection			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0

Viral infection			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	8 / 64 (12.50%)	7 / 74 (9.46%)	4 / 72 (5.56%)
occurrences (all)	12	7	4
Hyperglycaemia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 74 (1.35%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Hypokalaemia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 74 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Rybelsus 14mg (T2DM)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 73 (43.84%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Flushing			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
Asthenia			

subjects affected / exposed occurrences (all) Chest discomfort subjects affected / exposed occurrences (all) Early satiety subjects affected / exposed occurrences (all) Pain subjects affected / exposed occurrences (all)	0 / 73 (0.00%) 0 0 / 73 (0.00%) 0 0 / 73 (0.00%) 0 0 / 73 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all) Sinus congestion subjects affected / exposed occurrences (all)	 0 / 73 (0.00%) 0 0 / 73 (0.00%) 0 0 / 73 (0.00%) 0 0 / 73 (0.00%) 0		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all) Depressed mood subjects affected / exposed occurrences (all)	 0 / 73 (0.00%) 0 0 / 73 (0.00%) 0 0 / 73 (0.00%) 0		
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	3 / 73 (4.11%)		
occurrences (all)	3		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Liver function test increased			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Hepatic enzyme increased			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Amylase increased			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		

Headache			
subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
Dysgeusia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Head discomfort			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Abdominal pain upper			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
Constipation			
subjects affected / exposed	4 / 73 (5.48%)		
occurrences (all)	4		
Eructation			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Dyspepsia			

subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
Diarrhoea			
subjects affected / exposed	6 / 73 (8.22%)		
occurrences (all)	7		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	10 / 73 (13.70%)		
occurrences (all)	11		
Vomiting			
subjects affected / exposed	6 / 73 (8.22%)		
occurrences (all)	8		
Flatulence			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Abdominal discomfort			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Dry mouth			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Cholelithiasis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Microalbuminuria			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Haematuria			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Muscle spasms			
subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Osteoarthritis			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	4 / 73 (5.48%)		
occurrences (all)	5		
Upper respiratory tract infection			
subjects affected / exposed	3 / 73 (4.11%)		
occurrences (all)	3		
Sinusitis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
Ear infection			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		

Viral infection subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all)	0 / 73 (0.00%) 0 0 / 73 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) Hyperglycaemia subjects affected / exposed occurrences (all) Hypokalaemia subjects affected / exposed occurrences (all)	 0 / 73 (0.00%) 0 3 / 73 (4.11%) 4 2 / 73 (2.74%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

1 participant in placebo (T2DM) arm with withdrawal reason as Death in treatment phase was also counted in follow-up with the reason for discontinuation as death since exact date of last dose was unknown.

Notes: