Clinical trial results:
A randomized, placebo-controlled, participant-andinvestigator- blinded, sponsor open-label study to evaluate the safety, tolerability, and efficacy with different dosing regimens of subcutaneously administered MBL949 in obese participants with or without type 2 diabetes mellitus

Summary

EudraCT number	2021-004449-19
Trial protocol	DK
Global end of trial date	11 May 2023

Results information

Result version number	v1 (current)
This version publication date	19 May 2024
First version publication date	19 May 2024

Trial information

Trial identification

Sponsor protocol code	CMBL949A12201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05199090
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office , Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com
Scientific contact	Clinical Disclosure Office , Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.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	11 May 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 May 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objectives were:
• To evaluate the safety and tolerability of different dosing regimens of MBL949 in obese subjects with or without T2DM.
• To evaluate the effect of different dosing regimens of MBL949 on weight in obese subjects with or without T2DM at week 16.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 February 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 126
Worldwide total number of subjects	126
EEA total number of subjects	0

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)	126
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 4 research centers in United States participated in the study.

Pre-assignment

Screening details:

Participants underwent a screening visit between Day -35 and Day -15 to determine their eligibility for the study.
On Day 1, participants went to the clinic after an overnight fast of at least 10 hours to complete the Day 1 assessments prior to dosing.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	MBL949 Arm 1

Arm description:

MBL949 one 3 mg dose followed by two doses of 6 mg followed by five doses of 4.5 mg

Arm type	Experimental
Investigational medicinal product name	MBL949
Investigational medicinal product code	MBL949
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

MBL949 one 3 mg dose followed by two doses of 6 mg followed by five doses of4.5 mg

Arm title	MBL949 Arm 2

Arm description:

MBL949 two 3 mg doses followed by six doses of 4.5 mg

Arm type	Experimental
Investigational medicinal product name	MBL949
Investigational medicinal product code	MBL949
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

MBL949 two 3 mg doses followed by six doses of 4.5 mg

Arm title	MBL949 Arm 3

Arm description:

MBL949 one 12 mg dose followed by seven doses of 4.5 mg

Arm type	Experimental

Investigational medicinal product name	MBL949
Investigational medicinal product code	MBL949
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

MBL949 one 12 mg dose followed by seven doses of 4.5 mg

Arm title	MBL949 Arm 4

Arm description:

MBL949 one 1.5 mg dose followed by seven doses of 2.2 mg

Arm type	Experimental
Investigational medicinal product name	MBL949
Investigational medicinal product code	MBL949
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

MBL949 one 1.5 mg dose followed by seven doses of 2.2 mg

Arm title	MBL949 Arm 5

Arm description:

MBL949 one 3 mg dose followed by two doses of 6 mg followed by five doses of 7.5 mg

Arm type	Experimental
Investigational medicinal product name	MBL949
Investigational medicinal product code	MBL949
Other name	
Pharmaceutical forms	Solution for injection/infusion, Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

MBL949 one 3 mg dose followed by two doses of 6 mg followed by five doses of7.5 mg

Arm title	Placebo

Arm description:

Placebo to MBL949

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo to MBL949 formulated as solution for injection in vial for SC use

Number of subjects in period 1	MBL949 Arm 1	MBL949 Arm 2	MBL949 Arm 3
Started	14	22	16
Completed	12	8	15
Not completed	2	14	1
Physician decision	-	-	-

Adverse event, non-fatal	1	4	-
Subject decision	-	4	-
Study terminated by sponsor	-	6	-
Lost to follow-up	1	-	1

Number of subjects in period 1	MBL949 Arm 4	MBL949 Arm 5	Placebo
Started	15	15	44
Completed	9	10	31
Not completed	6	5	13
Physician decision	-	-	1
Adverse event, non-fatal	-	-	-
Subject decision	2	5	2
Study terminated by sponsor	-	-	5
Lost to follow-up	4	-	5

Baseline characteristics

Reporting groups	
Reporting group title	MBL949 Arm 1
Reporting group description:	
MBL949 one 3 mg dose followed by two doses of 6 mg followed by five doses of 4.5 mg	
Reporting group title	MBL949 Arm 2
Reporting group description:	
MBL949 two 3 mg doses followed by six doses of 4.5 mg	
Reporting group title	MBL949 Arm 3
Reporting group description:	
MBL949 one 12 mg dose followed by seven doses of 4.5 mg	
Reporting group title	MBL949 Arm 4
Reporting group description:	
MBL949 one 1.5 mg dose followed by seven doses of 2.2 mg	
Reporting group title	MBL949 Arm 5
Reporting group description:	
MBL949 one 3 mg dose followed by two doses of 6 mg followed by five doses of 7.5 mg	
Reporting group title	Placebo
Reporting group description:	
Placebo to MBL949	

Reporting group values	MBL949 Arm 1	MBL949 Arm 2	MBL949 Arm 3
Number of subjects	14	22	16
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	14	22	16
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	47.4	45.8	44.8
standard deviation	± 9.53	± 7.77	± 11.23
Sex: Female, Male Units: participants			
Female	8	17	13
Male	6	5	3
Race/Ethnicity, Customized Units: Subjects			
Black or African American	3	4	2
White	11	18	14

Reporting group values	MBL949 Arm 4	MBL949 Arm 5	Placebo
Number of subjects	15	15	44
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	15	15	44
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	45.8	41.6	44.0
standard deviation	± 8.98	± 10.68	± 10.09
Sex: Female, Male Units: participants			
Female	12	13	38
Male	3	2	6
Race/Ethnicity, Customized Units: Subjects			
Black or African American	6	3	11
White	9	12	33

Reporting group values	Total		
Number of subjects	126		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	126		
From 65-84 years	0		
85 years and over	0		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: participants			
Female	101		
Male	25		

Race/Ethnicity, Customized Units: Subjects			
Black or African American	29		
White	97		

End points

End points reporting groups

Reporting group title	MBL949 Arm 1
Reporting group description:	
MBL949 one 3 mg dose followed by two doses of 6 mg followed by five doses of 4.5 mg	
Reporting group title	MBL949 Arm 2
Reporting group description:	
MBL949 two 3 mg doses followed by six doses of 4.5 mg	
Reporting group title	MBL949 Arm 3
Reporting group description:	
MBL949 one 12 mg dose followed by seven doses of 4.5 mg	
Reporting group title	MBL949 Arm 4
Reporting group description:	
MBL949 one 1.5 mg dose followed by seven doses of 2.2 mg	
Reporting group title	MBL949 Arm 5
Reporting group description:	
MBL949 one 3 mg dose followed by two doses of 6 mg followed by five doses of 7.5 mg	
Reporting group title	Placebo
Reporting group description:	
Placebo to MBL949	
Subject analysis set title	Pooled MBL949
Subject analysis set type	Per protocol
Subject analysis set description:	
Pooled MBL949 arms	
Subject analysis set title	Pooled MBL949
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants from PD analysis set of the Pooled MBL949 arm with weight data at Baseline and Week 16 were included in the analysis.	

Primary: Frequency and severity of Adverse Events

End point title	Frequency and severity of Adverse Events[1]
End point description:	
Number of participants with adverse events reported after the first dose of study medication or events present prior to treatment but increase in severity	
End point type	Primary
End point timeframe:	
Baseline to Day 169	

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: No statistical analysis was planned for this primary outcome

End point values	MBL949 Arm 1	MBL949 Arm 2	MBL949 Arm 3	MBL949 Arm 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	22	16	15
Units: participants				
Total AEs	11	20	15	10
AEs of mild intensity	10	19	15	10
AEs of moderate intensity	4	8	7	3

AEs of severe intensity	0	2	0	1
Study drug-related AEs	9	18	15	8
Serious AEs	0	0	0	0

End point values	MBL949 Arm 5	Placebo	Pooled MBL949	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	15	44	82	
Units: participants				
Total AEs	14	30	70	
AEs of mild intensity	14	29	68	
AEs of moderate intensity	8	7	30	
AEs of severe intensity	0	2	3	
Study drug-related AEs	12	19	62	
Serious AEs	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Change-from-baseline in weight

End point title	Change-from-baseline in weight
End point description: Baseline weight is defined as the last weight measurement before dosing in kilograms	
End point type	Primary
End point timeframe: Week 16	

End point values	MBL949 Arm 1	MBL949 Arm 2	MBL949 Arm 3	MBL949 Arm 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	8	15	9
Units: kg				
arithmetic mean (confidence interval 90%)	-2.6 (-3.8 to -1.5)	-2.0 (-3.3 to -0.8)	-2.0 (-3.0 to -0.9)	-0.1 (-1.4 to 1.1)

End point values	MBL949 Arm 5	Placebo	Pooled MBL949	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	31	54	
Units: kg				
arithmetic mean (confidence interval 90%)	0.3 (-0.9 to 1.5)	-0.7 (-1.4 to -0.0)	-1.4 (-2.0 to -0.8)	

Statistical analyses

Statistical analysis title	MBL949 Arm 1 vs placebo
Statistical analysis description: Comparison of adjusted means	
Comparison groups	MBL949 Arm 1 v Placebo
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0182
Method	MMRM analysis
Parameter estimate	adjusted means
Point estimate	-1.9
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-2.9
upper limit	-0.9

Statistical analysis title	MBL949 Arm 2 vs placebo
Comparison groups	MBL949 Arm 2 v Placebo
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1205
Method	MMRM analysis
Parameter estimate	adjusted means
Point estimate	-1.3
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-2.4
upper limit	-0.2

Statistical analysis title	MBL949 Arm 3 vs placebo
Comparison groups	MBL949 Arm 3 v Placebo

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0931
Method	MMRM analysis
Parameter estimate	adjusted means
Point estimate	-1.3
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-2.2
upper limit	-0.3

Statistical analysis title	MBL949 Arm 4 vs placebo
Comparison groups	MBL949 Arm 4 v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4994
Method	MMRM analysis
Parameter estimate	adjusted means
Point estimate	0.6
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.5
upper limit	1.7

Statistical analysis title	MBL949 Arm 5 vs placebo
Comparison groups	MBL949 Arm 5 v Placebo
Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.2295
Method	MMRM analysis
Parameter estimate	adjusted means
Point estimate	1
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.1
upper limit	2.1

Statistical analysis title	Pooled MBL949 vs placebo

Comparison groups	Placebo v Pooled MBL949
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.2114
Method	MMRM analysis
Parameter estimate	adjusted means
Point estimate	-0.7
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-1.3
upper limit	0

Adverse events

Adverse events information

Timeframe for reporting adverse events:

erse events were reported from first dose of study treatment until end of study treatment plus 10 weeks post treatment, up to a maximum duration of 24 weeks.

Adverse event reporting additional description:

Each treatment arm contains a different dosing scheme and adverse event data is provided for the full sequence.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	MBL949 Arm 1
Reporting group description:	
MBL949 Arm 1	
Reporting group title	MBL949 Arm 2
Reporting group description:	
MBL949 Arm 2	
Reporting group title	MBL949 Arm 3
Reporting group description:	
MBL949 Arm 3	
Reporting group title	MBL949 Arm 4
Reporting group description:	
MBL949 Arm 4	
Reporting group title	MBL949 Arm 5
Reporting group description:	
MBL949 Arm 5	
Reporting group title	Pooled MBL949
Reporting group description:	
Pooled MBL949	
Reporting group title	Pooled Placebo
Reporting group description:	
Pooled Placebo	
Reporting group title	Total
Reporting group description:	
Total	

Serious adverse events	MBL949 Arm 1	MBL949 Arm 2	MBL949 Arm 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	MBL949 Arm 4	MBL949 Arm 5	Pooled MBL949
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 82 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Pooled Placebo	Total	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 44 (0.00%)	0 / 126 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	MBL949 Arm 1	MBL949 Arm 2	MBL949 Arm 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 14 (78.57%)	20 / 22 (90.91%)	15 / 16 (93.75%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	1 / 22 (4.55%)	2 / 16 (12.50%)
occurrences (all)	0	1	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)	5 / 22 (22.73%)	1 / 16 (6.25%)
occurrences (all)	0	6	1

Injection site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	4	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 14 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Investigations			
Pancreatic enzymes increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Cortisol free urine increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	3 / 14 (21.43%)	4 / 22 (18.18%)	2 / 16 (12.50%)
occurrences (all)	3	4	4
Taste disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Sinus headache			

subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Anal incontinence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 14 (21.43%)	5 / 22 (22.73%)	5 / 16 (31.25%)
occurrences (all)	3	5	5
Dental caries			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	2 / 22 (9.09%)	2 / 16 (12.50%)
occurrences (all)	0	6	2
Abdominal distension			
subjects affected / exposed	2 / 14 (14.29%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			

subjects affected / exposed	3 / 14 (21.43%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Frequent bowel movements			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 14 (7.14%)	10 / 22 (45.45%)	8 / 16 (50.00%)
occurrences (all)	1	14	18
Retching			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	9 / 14 (64.29%)	17 / 22 (77.27%)	14 / 16 (87.50%)
occurrences (all)	22	57	39
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 14 (7.14%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Ingrowing nail			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dermatitis contact			

subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Bacterial vaginosis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 14 (0.00%)	3 / 22 (13.64%)	1 / 16 (6.25%)
occurrences (all)	0	3	1
COVID-19			
subjects affected / exposed	0 / 14 (0.00%)	1 / 22 (4.55%)	4 / 16 (25.00%)
occurrences (all)	0	1	4
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	3 / 22 (13.64%)	2 / 16 (12.50%)
occurrences (all)	0	3	2
Tinea cruris			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 22 (4.55%)	2 / 16 (12.50%)
occurrences (all)	0	1	2
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Decreased appetite			
subjects affected / exposed	1 / 14 (7.14%)	0 / 22 (0.00%)	3 / 16 (18.75%)
occurrences (all)	1	0	3
Hypoglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Food aversion			
subjects affected / exposed	0 / 14 (0.00%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	MBL949 Arm 4	MBL949 Arm 5	Pooled MBL949
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 15 (66.67%)	14 / 15 (93.33%)	70 / 82 (85.37%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	4 / 82 (4.88%)
occurrences (all)	0	1	4
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Chest discomfort			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 82 (2.44%)
occurrences (all)	0	1	2
Fatigue			

subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	8 / 82 (9.76%)
occurrences (all)	1	1	9
Injection site pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	3 / 82 (3.66%)
occurrences (all)	0	1	6
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 82 (2.44%)
occurrences (all)	0	1	2
Oropharyngeal pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	2 / 82 (2.44%)
occurrences (all)	1	0	2
Investigations			
Pancreatic enzymes increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Lipase increased			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Cortisol free urine increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Procedural pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Muscle contusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	3 / 82 (3.66%)
occurrences (all)	0	1	3
Headache			
subjects affected / exposed	2 / 15 (13.33%)	3 / 15 (20.00%)	14 / 82 (17.07%)
occurrences (all)	2	3	16
Taste disorder			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Sinus headache			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 82 (2.44%)
occurrences (all)	0	1	2
Syncope			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Visual impairment			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	3 / 82 (3.66%)
occurrences (all)	0	1	3
Anal incontinence			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	1 / 15 (6.67%)	2 / 15 (13.33%)	16 / 82 (19.51%)
occurrences (all)	1	2	16
Dental caries			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	6 / 82 (7.32%)
occurrences (all)	0	4	12
Abdominal distension			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	3 / 82 (3.66%)
occurrences (all)	0	1	3
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	5 / 82 (6.10%)
occurrences (all)	0	2	5
Frequent bowel movements			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	2 / 82 (2.44%)
occurrences (all)	1	1	2
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	6 / 15 (40.00%)	7 / 15 (46.67%)	32 / 82 (39.02%)
occurrences (all)	7	12	52
Retching			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	6 / 15 (40.00%)	12 / 15 (80.00%)	58 / 82 (70.73%)
occurrences (all)	11	44	173
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	3 / 82 (3.66%)
occurrences (all)	0	0	3
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Ingrowing nail			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	2 / 82 (2.44%)
occurrences (all)	1	0	2
Joint swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 82 (2.44%)
occurrences (all)	0	0	2
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Bacterial vaginosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Viral infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	4 / 82 (4.88%)
occurrences (all)	0	0	4
COVID-19			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	6 / 82 (7.32%)
occurrences (all)	1	0	6
Conjunctivitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	1	0	1
Fungal foot infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	1 / 15 (6.67%)	3 / 15 (20.00%)	9 / 82 (10.98%)
occurrences (all)	1	3	9
Tinea cruris			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	5 / 82 (6.10%)
occurrences (all)	1	1	5
Urinary tract infection			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	2 / 82 (2.44%)
occurrences (all)	1	1	2

Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	5 / 82 (6.10%)
occurrences (all)	0	1	5
Hypoglycaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	2 / 82 (2.44%)
occurrences (all)	2	0	3
Hypertriglyceridaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 82 (1.22%)
occurrences (all)	0	1	1
Hyperlipidaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 82 (1.22%)
occurrences (all)	0	0	1
Food aversion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 82 (2.44%)
occurrences (all)	0	0	2

Non-serious adverse events	Pooled Placebo	Total	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 44 (59.09%)	96 / 126 (76.19%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 44 (0.00%)	4 / 126 (3.17%)	
occurrences (all)	0	4	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Chest discomfort			

subjects affected / exposed	0 / 44 (0.00%)	2 / 126 (1.59%)	
occurrences (all)	0	2	
Fatigue			
subjects affected / exposed	0 / 44 (0.00%)	8 / 126 (6.35%)	
occurrences (all)	0	9	
Injection site pain			
subjects affected / exposed	2 / 44 (4.55%)	3 / 126 (2.38%)	
occurrences (all)	2	3	
Oedema peripheral			
subjects affected / exposed	1 / 44 (2.27%)	2 / 126 (1.59%)	
occurrences (all)	1	2	
Injection site reaction			
subjects affected / exposed	2 / 44 (4.55%)	5 / 126 (3.97%)	
occurrences (all)	4	10	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 44 (2.27%)	3 / 126 (2.38%)	
occurrences (all)	1	3	
Oropharyngeal pain			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 44 (0.00%)	2 / 126 (1.59%)	
occurrences (all)	0	2	
Investigations			
Pancreatic enzymes increased			

subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Lipase increased			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Cortisol free urine increased			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Procedural pain			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Muscle contusion			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Ligament sprain			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Skin abrasion			
subjects affected / exposed	1 / 44 (2.27%)	2 / 126 (1.59%)	
occurrences (all)	1	2	
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Dysgeusia			
subjects affected / exposed	1 / 44 (2.27%)	4 / 126 (3.17%)	
occurrences (all)	1	4	
Headache			

subjects affected / exposed	1 / 44 (2.27%)	15 / 126 (11.90%)	
occurrences (all)	1	17	
Taste disorder			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Sinus headache			
subjects affected / exposed	0 / 44 (0.00%)	2 / 126 (1.59%)	
occurrences (all)	0	2	
Syncope			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Visual impairment			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 44 (0.00%)	3 / 126 (2.38%)	
occurrences (all)	0	3	
Anal incontinence			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	2 / 44 (4.55%)	18 / 126 (14.29%)	
occurrences (all)	2	18	
Dental caries			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Diarrhoea			

subjects affected / exposed	5 / 44 (11.36%)	11 / 126 (8.73%)	
occurrences (all)	10	22	
Abdominal distension			
subjects affected / exposed	5 / 44 (11.36%)	8 / 126 (6.35%)	
occurrences (all)	5	8	
Abdominal pain			
subjects affected / exposed	1 / 44 (2.27%)	6 / 126 (4.76%)	
occurrences (all)	2	7	
Frequent bowel movements			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Flatulence			
subjects affected / exposed	1 / 44 (2.27%)	3 / 126 (2.38%)	
occurrences (all)	1	3	
Dyspepsia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Gastritis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	3 / 44 (6.82%)	35 / 126 (27.78%)	
occurrences (all)	3	55	
Retching			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	17 / 44 (38.64%)	75 / 126 (59.52%)	
occurrences (all)	27	200	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 44 (0.00%)	3 / 126 (2.38%)	
occurrences (all)	0	3	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	

Skin and subcutaneous tissue disorders			
Ingrowing nail			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Dermatitis contact			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Dermatitis atopic			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Urticaria			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	1 / 44 (2.27%)	2 / 126 (1.59%)	
occurrences (all)	1	2	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Haematuria			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 44 (0.00%)	2 / 126 (1.59%)	
occurrences (all)	0	2	
Joint swelling			
subjects affected / exposed	1 / 44 (2.27%)	2 / 126 (1.59%)	
occurrences (all)	1	2	
Back pain			
subjects affected / exposed	0 / 44 (0.00%)	2 / 126 (1.59%)	
occurrences (all)	0	2	
Arthralgia			
subjects affected / exposed	3 / 44 (6.82%)	4 / 126 (3.17%)	
occurrences (all)	5	6	

Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Bacterial vaginosis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Viral infection			
subjects affected / exposed	0 / 44 (0.00%)	4 / 126 (3.17%)	
occurrences (all)	0	4	
COVID-19			
subjects affected / exposed	6 / 44 (13.64%)	12 / 126 (9.52%)	
occurrences (all)	6	12	
Conjunctivitis			
subjects affected / exposed	1 / 44 (2.27%)	2 / 126 (1.59%)	
occurrences (all)	1	2	
Fungal foot infection			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Gastroenteritis viral			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Sinusitis			
subjects affected / exposed	1 / 44 (2.27%)	10 / 126 (7.94%)	
occurrences (all)	1	10	
Tinea cruris			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	3 / 44 (6.82%)	8 / 126 (6.35%)	
occurrences (all)	5	10	
Urinary tract infection			

subjects affected / exposed	0 / 44 (0.00%)	2 / 126 (1.59%)	
occurrences (all)	0	2	
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Decreased appetite			
subjects affected / exposed	3 / 44 (6.82%)	8 / 126 (6.35%)	
occurrences (all)	3	8	
Hypoglycaemia			
subjects affected / exposed	0 / 44 (0.00%)	2 / 126 (1.59%)	
occurrences (all)	0	3	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Hyperlipidaemia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 126 (0.79%)	
occurrences (all)	0	1	
Food aversion			
subjects affected / exposed	0 / 44 (0.00%)	2 / 126 (1.59%)	
occurrences (all)	0	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 November 2021	The purpose of this amendment was to provide an update to the exclusion criteria for liver and renal parameters including cholelithiasis and pancreatitis.
01 January 2022	The purpose of this amendment was to update the PK sampling time points during the trial to adequately inform and characterize the PK profile of MBL949. The additional time points included the following: 24 h and 144 h post first dose (Day 2 and Day 7), and 144 h post eighth dose (Day 105). ADA were planned at pre-dose and end of study. However, to better understand the potential effect of MBL949 on immunogenicity over the course of the study, increased frequency of ADA measurements were added and coincided with the PK sampling time points.

Notes:

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.

The tolerability to benefit ratio based on maximum weight loss observed was not considered favorable at the doses studied and the study was terminated early.

Notes: