Clinical trial results:
A MulticenteR, Open-Label, First-in-Human, PhaSe Ib/IIa Trial of EO2401, a Novel Multipeptide Therapeutic VAccine, with and without PD-1 Check Point Inhibitor, FoLlowing Standard Treatment in Patlents with ProgrEssive Glioblastoma (Rosalie study)

Summary

EudraCT number	2018-002279-16
Trial protocol	DE ES
Global end of trial date	04 March 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	EOGBM1-18

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04116658
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Enterome
Sponsor organisation address	94/96 avenue Ledru-Rollin , Paris, France,
Public contact	Jan Fagerberg, Enterome, info@enterome.com
Scientific contact	Jan Fagerberg, Enterome, info@enterome.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	04 March 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 March 2024
Global end of trial reached?	Yes
Global end of trial date	04 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this first-in-human (FIH) trial of EO2401 is to evaluate the safety and tolerability of EO2401 as monotherapy and in combination with nivolumab, and nivolumab/bevacizumab in patients with progressive glioblastoma (GB). The safety and tolerability evaluation include assessments of different patient populations within the group of patients with recurrent GB: i) Cohorts 1a, 2a, and 3 evaluate patients with measurable disease, ii) Cohort 2b evaluates patients with non-measurable disease (after surgery of recurrent disease, i.e. adjuvant treatment), and iii) Cohort 2c evaluates a neoadjuvant/surgery/adjuvant treatment concept.

Protection of trial subjects:

IDMC will support the safety monitoring and give recommendations for possible actions in relation to trial conduct actions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 July 2020
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	Spain: 19
Country: Number of subjects enrolled	France: 28
Country: Number of subjects enrolled	Germany: 29
Country: Number of subjects enrolled	United States: 24
Worldwide total number of subjects	100
EEA total number of subjects	76

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)	77
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

76 patients treated in EU and 24 patients in US from July 2020 to Nov 2022.
10 clinical investigational sites which screened at least one patient (9 sites in Europe and 1 site in US).

Pre-assignment

Screening details:

Patient HLA-A2+ with recurrent glioblastoma

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	All Cohorts

Arm description: -

Arm type	Experimental
Investigational medicinal product name	EO2401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

1 mL

Number of subjects in period 1	All Cohorts
Started	100
Completed	100

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	100	100	
Age categorical Units: Subjects			
Adults (18-64 years)	77	77	
From 65-84 years	23	23	
Gender categorical Units: Subjects			
Female	38	38	
Male	62	62	

Subject analysis sets

Subject analysis set title	All patient population
Subject analysis set type	Full analysis

Subject analysis set description:

Patients who received at least one dose of EO2401

Reporting group values	All patient population		
Number of subjects	100		
Age categorical Units: Subjects			
Adults (18-64 years)	77		
From 65-84 years	23		
Gender categorical Units: Subjects			
Female	38		
Male	62		

End points

End points reporting groups

Reporting group title	All Cohorts
Reporting group description: -	
Subject analysis set title	All patient population
Subject analysis set type	Full analysis
Subject analysis set description:	
Patients who received at least one dose of EO2401	

Primary: Incidences of Serious Adverse Events (SAEs) using the National Cancer Institute-Common Terminology Criteria for AEs (NCI-CTCAE) v5.0

End point title	Incidences of Serious Adverse Events (SAEs) using the National Cancer Institute-Common Terminology Criteria for AEs (NCI-CTCAE) v5.0[1]
End point description:	

End point type	Primary
End point timeframe:	
44 months (from first patient enrolled to last patient last visit)	

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: single arm study

End point values	All patient population			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: events	32			

Statistical analyses

No statistical analyses for this end point

Primary: Incidences of non Serious AEs using the National Cancer Institute-Common Terminology Criteria for AEs (NCI-CTCAE) v5.0

End point title	Incidences of non Serious AEs using the National Cancer Institute-Common Terminology Criteria for AEs (NCI-CTCAE) v5.0[2]
End point description:	

End point type	Primary
End point timeframe:	
44 months (from first patient enrolled to last patient last visit)	

Notes:

[2] - 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: single arm study

End point values	All patient population			
Subject group type	Subject analysis set			
Number of subjects analysed	100			
Units: events	241			

Statistical analyses

No statistical analyses for this end point

Primary: Number of deaths

End point title	Number of deaths[3]

End point description:

End point type	Primary

End point timeframe:

44 months (from first patient enrolled to last patient last visit)

Notes:

[3] - 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: single arm study

End point values	All patient population			
Subject group type	Subject analysis set			
Number of subjects analysed	100			
Units: number of patients	89			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Timeframe for Treatment-Emergent AE

Adverse event reporting additional description:

Treatment- Emergent AE additional description

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	All patient population

Reporting group description: -

Serious adverse events	All patient population		
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 100 (25.00%)		
number of deaths (all causes)	89		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon	Additional description: Adenocarcinoma of colon		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to liver	Additional description: Metastases to liver		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall	Additional description: Fall		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture	Additional description: Radius fracture		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis	Additional description: Venous thrombosis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Haemorrhage intracranial	Additional description: Haemorrhage intracranial		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Epilepsy	Additional description: Epilepsy		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident	Additional description: Cerebrovascular accident		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain oedema	Additional description: Brain oedema		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure	Additional description: Seizure		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Headache	Additional description: Headache		

subjects affected / exposed	2 / 100 (2.00%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke	Additional description: Ischaemic stroke		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Status epilepticus	Additional description: Status epilepticus		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Neurological decompensation	Additional description: Neurological decompensation		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Motor dysfunction	Additional description: Motor dysfunction		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Condition aggravated	Additional description: Condition aggravated		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chills	Additional description: Chills		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration	Additional description: General physical health deterioration		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Lower gastrointestinal haemorrhage	Additional description: Lower gastrointestinal haemorrhage		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea	Additional description: Nausea		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Confusional state	Additional description: Confusional state		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Bone pain	Additional description: Bone pain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune-mediated arthritis	Additional description: Immune-mediated arthritis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Muscular weakness	Additional description: Muscular weakness		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myalgia	Additional description: Myalgia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection	Additional description: Wound infection		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Meningitis aseptic	Additional description: Meningitis aseptic		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration	Additional description: Dehydration		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	All patient population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	98 / 100 (98.00%)		
Vascular disorders			
Hypotension	Additional description: Hypotension		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	3		
Hypertension	Additional description: Hypertension		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	8		
Haematoma	Additional description: Haematoma		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
General disorders and administration site conditions			
Localised oedema	Additional description: Localised oedema		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Injection site granuloma	Additional description: Injection site granuloma		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Injection site haematoma	Additional description: Injection site haematoma		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	4		
Influenza like illness	Additional description: Influenza like illness		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	4		
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Chills	Additional description: Chills		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	6		
Injection site pain	Additional description: Injection site pain		

subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	7		
Injection site induration	Additional description: Injection site induration		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	8		
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	10		
Injection site erythema	Additional description: Injection site erythema		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	13		
Asthenia	Additional description: Asthenia		
subjects affected / exposed	8 / 100 (8.00%)		
occurrences (all)	16		
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	12 / 100 (12.00%)		
occurrences (all)	18		
Fatigue	Additional description: Fatigue		
subjects affected / exposed	28 / 100 (28.00%)		
occurrences (all)	33		
Injection site reaction	Additional description: Injection site reaction		
subjects affected / exposed	28 / 100 (28.00%)		
occurrences (all)	66		
Local reaction	Additional description: Local reaction		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Chest pain	Additional description: Chest pain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Disease progression	Additional description: Disease progression		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Face oedema	Additional description: Face oedema		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Injection site discharge	Additional description: Injection site discharge		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Injection site discomfort	Additional description: Injection site discomfort		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Injection site inflammation	Additional description: Injection site inflammation		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Injection site nodule	Additional description: Injection site nodule		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Injection site pruritus	Additional description: Injection site pruritus		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Injection site swelling	Additional description: Injection site swelling		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Medical device site fistula	Additional description: Medical device site fistula		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Mucosal inflammation	Additional description: Mucosal inflammation		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Non-cardiac chest pain	Additional description: Non-cardiac chest pain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Pain	Additional description: Pain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Immune system disorders			
Hypersensitivity	Additional description: Hypersensitivity		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	4		
Reproductive system and breast disorders			

Benign prostatic hyperplasia	Additional description: Benign prostatic hyperplasia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Dysphonia	Additional description: Dysphonia		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Cough	Additional description: Cough		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	7		
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Nasal congestion	Additional description: Nasal congestion		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Aphonia	Additional description: Aphonia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Respiratory disorder	Additional description: Respiratory disorder		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Bronchospasm	Additional description: Bronchospasm		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Psychiatric disorders			
Anxiety	Additional description: Anxiety		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	7		
Insomnia	Additional description: Insomnia		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	7		
Confusional state	Additional description: Confusional state		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	11		
Depression	Additional description: Depression		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Bradyphrenia	Additional description: Bradyphrenia		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	6		
Agitation	Additional description: Agitation		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	3		
Disorientation	Additional description: Disorientation		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	6		
Affect lability	Additional description: Affect lability		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Learning disorder	Additional description: Learning disorder		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Mutism	Additional description: Mutism		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Investigations			
Blood pressure increased	Additional description: Blood pressure increased		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Blood cholesterol increased	Additional description: Blood cholesterol increased		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Blood thyroid stimulating hormone decreased	Additional description: Blood thyroid stimulating hormone decreased		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	6		
Platelet count decreased	Additional description: Platelet count decreased		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	9		
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	9		
Blood thyroid stimulating hormone increased	Additional description: Blood thyroid stimulating hormone increased		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	7		
Neutrophil count decreased	Additional description: Neutrophil count decreased		

subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	11		
White blood cell count decreased	Additional description: White blood cell count decreased		
subjects affected / exposed	8 / 100 (8.00%)		
occurrences (all)	11		
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	11 / 100 (11.00%)		
occurrences (all)	18		
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	15 / 100 (15.00%)		
occurrences (all)	19		
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	18 / 100 (18.00%)		
occurrences (all)	24		
Lymphocyte count decreased	Additional description: Lymphocyte count decreased		
subjects affected / exposed	19 / 100 (19.00%)		
occurrences (all)	52		
Blood urea increased	Additional description: Blood urea increased		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
SARS-CoV-2 test positive	Additional description: SARS-CoV-2 test positive		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Thyroxine decreased	Additional description: Thyroxine decreased		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Thyroxine increased	Additional description: Thyroxine increased		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Troponin T increased	Additional description: Troponin T increased		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			

Infusion related reaction	Additional description: Infusion related reaction		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Bone fissure	Additional description: Bone fissure		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Fall	Additional description: Fall		
subjects affected / exposed	13 / 100 (13.00%)		
occurrences (all)	18		
Ligament sprain	Additional description: Ligament sprain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Wrist fracture	Additional description: Wrist fracture		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Wound complication	Additional description: Wound complication		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Vaccination complication	Additional description: Vaccination complication		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Skin abrasion	Additional description: Skin abrasion		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Cardiac disorders			
Conduction disorder	Additional description: Conduction disorder		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Nervous system disorders			
Clumsiness	Additional description: Clumsiness		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Headache	Additional description: Headache		
subjects affected / exposed	29 / 100 (29.00%)		
occurrences (all)	50		
Hemiparesis	Additional description: Hemiparesis		

subjects affected / exposed	17 / 100 (17.00%)		
occurrences (all)	24		
Aphasia	Additional description: Aphasia		
subjects affected / exposed	16 / 100 (16.00%)		
occurrences (all)	23		
Seizure	Additional description: Seizure		
subjects affected / exposed	12 / 100 (12.00%)		
occurrences (all)	26		
Dizziness	Additional description: Dizziness		
subjects affected / exposed	9 / 100 (9.00%)		
occurrences (all)	12		
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	8 / 100 (8.00%)		
occurrences (all)	10		
Hemianopia	Additional description: Hemianopia		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Memory impairment	Additional description: Memory impairment		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Epilepsy	Additional description: Epilepsy		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	5		
Neurological decompensation	Additional description: Neurological decompensation		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Partial seizures	Additional description: Partial seizures		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	7		
Apraxia	Additional description: Apraxia		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	4		
Ataxia	Additional description: Ataxia		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	4		
Tremor	Additional description: Tremor		

subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	4		
Amnesia	Additional description: Amnesia		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Brain oedema	Additional description: Brain oedema		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Cognitive disorder	Additional description: Cognitive disorder		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Quadrantanopia	Additional description: Quadrantanopia		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Somnolence	Additional description: Somnolence		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Alexia	Additional description: Alexia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	2		
Dysdiadochokinesis	Additional description: Dysdiadochokinesis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	2		
Fine motor skill dysfunction	Additional description: Fine motor skill dysfunction		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	2		
Monoparesis	Additional description: Monoparesis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	2		
Brain injury	Additional description: Brain injury		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Dysgeusia	Additional description: Dysgeusia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Haemorrhage intracranial	Additional description: Haemorrhage intracranial		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Hemihypoaesthesia	Additional description: Hemihypoaesthesia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Hypoaesthesia	Additional description: Hypoaesthesia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Language disorder	Additional description: Language disorder		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Nervous system disorder	Additional description: Nervous system disorder		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Pyramidal tract syndrome	Additional description: Pyramidal tract syndrome		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Restless legs syndrome	Additional description: Restless legs syndrome		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Vibratory sense increased	Additional description: Vibratory sense increased		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Facial paresis	Additional description: Facial paresis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	9 / 100 (9.00%)		
occurrences (all)	12		
Lymphopenia	Additional description: Lymphopenia		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		

Neutropenia	Additional description: Neutropenia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Ear discomfort	Additional description: Ear discomfort		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Vertigo	Additional description: Vertigo		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Eye disorders			
Visual impairment	Additional description: Visual impairment		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	4		
Diplopia	Additional description: Diplopia		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Visual field defect	Additional description: Visual field defect		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Vitreous floaters	Additional description: Vitreous floaters		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Vision blurred	Additional description: Vision blurred		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Eyelid ptosis	Additional description: Eyelid ptosis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Eye haematoma	Additional description: Eye haematoma		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Blepharitis	Additional description: Blepharitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Conjunctival haemorrhage	Additional description: Conjunctival haemorrhage		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	2		
Gastrointestinal disorders			
Dysphagia	Additional description: Dysphagia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Dental caries	Additional description: Dental caries		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Angular cheilitis	Additional description: Angular cheilitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Anal erythema	Additional description: Anal erythema		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	3		
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	10		
Vomiting	Additional description: Vomiting		
subjects affected / exposed	8 / 100 (8.00%)		
occurrences (all)	9		

Constipation	Additional description: Constipation		
subjects affected / exposed	9 / 100 (9.00%)		
occurrences (all)	10		
Nausea	Additional description: Nausea		
subjects affected / exposed	12 / 100 (12.00%)		
occurrences (all)	15		
Faeces discoloured	Additional description: Faeces discoloured		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Stomatitis	Additional description: Stomatitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Intestinal mass	Additional description: Intestinal mass		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Ileus	Additional description: Ileus		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Gingival pain	Additional description: Gingival pain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Hepatobiliary disorders			
Cholelithiasis	Additional description: Cholelithiasis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Hepatotoxicity	Additional description: Hepatotoxicity		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Pruritus	Additional description: Pruritus		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	7		
Erythema	Additional description: Erythema		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Rash	Additional description: Rash		

subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Skin reaction	Additional description: Skin reaction		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	3		
Eczema	Additional description: Eczema		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Rash erythematous	Additional description: Rash erythematous		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Toxic skin eruption	Additional description: Toxic skin eruption		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	2		
Cellulite	Additional description: Cellulite		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Dermatitis	Additional description: Dermatitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Dermatitis allergic	Additional description: Dermatitis allergic		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Dry skin	Additional description: Dry skin		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Immune-mediated dermatitis	Additional description: Immune-mediated dermatitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Pain of skin	Additional description: Pain of skin		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Penile ulceration	Additional description: Penile ulceration		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Petechiae	Additional description: Petechiae		

subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Rash macular	Additional description: Rash macular		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Rash maculo-papular	Additional description: Rash maculo-papular		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Rash papular	Additional description: Rash papular		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Rosacea	Additional description: Rosacea		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Vitiligo	Additional description: Vitiligo		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Renal and urinary disorders			
Proteinuria	Additional description: Proteinuria		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	14		
Urinary incontinence	Additional description: Urinary incontinence		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Glycosuria	Additional description: Glycosuria		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Chronic kidney disease	Additional description: Chronic kidney disease		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Haematuria	Additional description: Haematuria		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		

Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Endocrine disorders			
Hypothyroidism	Additional description: Hypothyroidism		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	7		
Adrenal insufficiency	Additional description: Adrenal insufficiency		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	9		
Hyperthyroidism	Additional description: Hyperthyroidism		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	6		
Androgen deficiency	Additional description: Androgen deficiency		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Back pain	Additional description: Back pain		
subjects affected / exposed	8 / 100 (8.00%)		
occurrences (all)	9		
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	7 / 100 (7.00%)		
occurrences (all)	9		
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Muscular weakness	Additional description: Muscular weakness		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Myalgia	Additional description: Myalgia		
subjects affected / exposed	5 / 100 (5.00%)		
occurrences (all)	5		
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	5		
Osteoarthritis	Additional description: Osteoarthritis		

subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Arthritis	Additional description: Arthritis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	3		
Mobility decreased	Additional description: Mobility decreased		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Neck pain	Additional description: Neck pain		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Pain in jaw	Additional description: Pain in jaw		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Torticollis	Additional description: Torticollis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Plantar fasciitis	Additional description: Plantar fasciitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Infections and infestations			
Wound infection	Additional description: Wound infection		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Acne pustular	Additional description: Acne pustular		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Coronavirus infection	Additional description: Coronavirus infection		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	6		
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	6		

COVID-19	Additional description: COVID-19		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Cystitis	Additional description: Cystitis		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Injection site infection	Additional description: Injection site infection		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Tooth abscess	Additional description: Tooth abscess		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Conjunctivitis	Additional description: Conjunctivitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Scrotal infection	Additional description: Scrotal infection		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Rhinitis	Additional description: Rhinitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Respiratory tract infection	Additional description: Respiratory tract infection		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Pustule	Additional description: Pustule		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		

Periodontitis	Additional description: Periodontitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Paronychia	Additional description: Paronychia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Gingivitis	Additional description: Gingivitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Genital infection fungal	Additional description: Genital infection fungal		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Fungal skin infection	Additional description: Fungal skin infection		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Folliculitis	Additional description: Folliculitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	9 / 100 (9.00%)		
occurrences (all)	15		
Hypocalcaemia	Additional description: Hypocalcaemia		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	14		
Hypokalaemia	Additional description: Hypokalaemia		
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	7		
Decreased appetite	Additional description: Decreased appetite		

subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	6		
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	8		
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	4 / 100 (4.00%)		
occurrences (all)	4		
Hypomagnesaemia	Additional description: Hypomagnesaemia		
subjects affected / exposed	3 / 100 (3.00%)		
occurrences (all)	5		
Hypercalcaemia	Additional description: Hypercalcaemia		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Hypernatraemia	Additional description: Hypernatraemia		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	2 / 100 (2.00%)		
occurrences (all)	2		
Dehydration	Additional description: Dehydration		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Hyperuricaemia	Additional description: Hyperuricaemia		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Hypovitaminosis	Additional description: Hypovitaminosis		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Iron deficiency	Additional description: Iron deficiency		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		
Vitamin D deficiency	Additional description: Vitamin D deficiency		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 September 2019	Country: FRANCE Modifications of the protocol following ANSM / French EC review
26 September 2019	Country: GERMANY Modifications of the protocol following PEI / Medical Faculty of Heidelberg's EC review
26 September 2019	Country: SPAIN Modifications of the protocol following AEMPS review
04 May 2020	Country: USA Modifications of the US protocol for administrative reasons
28 September 2020	This global amendment introduced two main changes as compared to the versions previously approved in France, Germany, Spain and the USA: • Introduction of a two-step screening procedure: 1st HLA A2 patients screening; 2nd Screening per se for patients eligible to participate to the whole study based on results of the HLA A2 screening step • Split of cohort 2 in two cohorts, 2a and 2b where patients to be included under cohort 2a should have at least one measurable lesion and patients to be included under cohort 2b should not have measurable enhancing disease Note: amendment date is 23 March 2020 for EUROPE and 28 September for USA
17 August 2021	This global amendment main changes included: • Addition of 12 patients to Cohort 1a • Addition of 10 patients to Cohort 2a without any change of the schedule or inclusion criteria (i.e. measurable disease), and extend patient management measures • Addition of a Cohort 2c for neoadjuvant (EO2401+ nivolumab administered twice with 2 weeks interval, then planned surgery = patient population is "intended for surgery of recurrent disease")/adjuvant (planned if feasible post-surgery; EO2401+ nivolumab administered twice with 2 weeks interval, then switch to EO2401 on 4-weekly schedule and continued nivolumab 2-weekly) including 6 patients, and extended patient management measures as in the other cohorts • Inclusion of immune testing at the visit after the first EO2401 administration (V2) • Extended patient management for significant neurological symptoms
27 April 2022	This global amendment main changes included: • Addition of 15 patients to Cohort 3 and broadening of recruitment for the cohort outside of the USA. • Adjustments related to a clarifying Note-to-File (NTF) regarding redistribution of patients between cohorts which was submitted to the study documentation March 10, 2022, i.e., after protocol EOGBM1-18 version 3 was implemented.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported