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A study of cibisatamab in participants with locally advanced and/or metastatic carcinoembryonic antigen positive solid tumors

Submission date
23/02/2021

Recruitment status
No longer recruiting

Registration date
22/06/2021

Overall study status
Completed

Last Edited
23/06/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary

Background and study aims
The aim of this study is to evaluate the safety, side effects, and effectiveness of the drug cibisatamab in participants with locally advanced and/or metastatic carcinoembryonic antigen (CEA) positive solid tumors who have progressed on standard treatment, are intolerant to standard of care (SOC), and/or are not responsive to SOC. Locally advanced cancer is cancer that has spread only to nearby tissues or lymph nodes, while metastatic cancer is cancer that has spread to other parts of the body. CEAs are substances (usually proteins) that are produced by some types of cancer.

Who can participate?
Patients with locally advanced and/or metastatic CEA-positive solid tumors

What does the study involve?
Part I of the study will investigate the safety and pharmacokinetics (processing by the body) of a single dose of cibisatamab starting from a minimal dose of 0.05 mg and up to a maximum dose of 2.5 mg. Part II will establish the appropriate dose for treatment based on safety, pharmacokinetics, and the maximum tolerated dose of cibisatamab with or without obinutuzumab for the once per week treatment, every three weeks treatment, and for the step-up dosing treatment.

What are the possible benefits and risks of participating?
Cibisatamab is expected to have anti-cancer properties and the pretreatment with obinutuzumab could provide a meaningful clinical benefit in patients with cancer. Potential side effects for cibisatamab and obinutuzumab include gastrointestinal (GI) side effects (diarrhea), breathing side effects (shortness of breath and lack of oxygen), and blood side effects (low white blood cell count and low red blood cell count).

Where is the study run from?
Hospitals in the United States, Canada, Denmark, Italy, Netherlands and Spain

When is the study starting and how long is it expected to run for?
May 2014 to September 2019

Who is funding the study?
Genentech (USA)

Who is the main contact?
global-roche-genentech-trials@gene.com

Study website
https://forpatients.roche.com/en/trials/cancer/solid-tumors/a-study-of-ro6958688-in-participants-with-locally-advan-08287.html

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
2014-003075-30

IRAS number

ClinicalTrials.gov number
NCT02324257

Secondary identifying numbers
BP29541

Study information

Scientific Title
An open-label, multicenter, dose-escalation Phase I study to evaluate the safety, pharmacokinetics, and therapeutic activity of cibisatamab, a novel T-cell bispecific antibody that targets the human carcinoembryonic antigen (CEA) on tumor cells and CD3 on T cells, administered intravenously in patients with locally advanced and/or metastatic CEA(+) solid tumors

Study hypothesis
To evaluate the safety, tolerability and clinical activity of single-agent cibisatamab in participants with locally advanced and/or metastatic carcinoembryonic antigen (CEA) positive solid tumors who have progressed on standard treatment, are intolerant to standard of care (SOC), and/or are non-amenable to SOC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/12/2014, Ethics Committee for Clinical Investigation of Hospital Universitari Vall d' Hebron (Passeig Vall D'hebrón, 119-129 - Edificio Materno-Infantil 13th Floor, 08035, Barcelona, Spain; +34 (0)934894010; ceic@ir.vhebron.net), ref: ID-RTF010

Study design
Interventional non-randomized trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Condition
Solid tumors

Interventions
The study will be conducted in two parts. Part I of the study will investigate the safety and pharmacokinetics of a single dose of cibisatamab in single participant cohorts with dosing starting from a minimal anticipated biological effect level dose of 0.05 milligrams (mg) and up to a maximum dose of 2.5 mg. Part II will establish the appropriate therapeutic dose based on safety, pharmacokinetics, and the maximum tolerated dose (MTD) of cibisatamab for the once per week (QW) regimen, every 3 weeks (Q3W) regimen, and for the step-up dosing regimen.

Part I:
Participants will receive a single dose of cibisatamab starting from a dose of 0.05, 0.15, 0.45, 1.3, and 2.5 mg.
Cibisatamab is given as an intravenous (IV) infusion as a single administration.
Tocilizumab will be administered as an IV infusion as necessary to treat adverse events.

Part II:
Participants will receive cibisatamab with or without obinutuzumab pretreatment QW, Q3W, or according to a combined QW/Q3W step-up dosing schedule. Doses will start at 40 mg and increase with each administration up to the MTD or 1200 mg, whichever is lower.
Cibisatamab is given as an intravenous (IV) infusion as a combined QW/Q3W step-up dosing regimen (cycle = 7 days in the QW regimen and cycle = 21 days in the Q3W regimen).
Obinutuzumab is given as an IV infusion at a dose level of 2000 mg on Day -13 or 1000 mg on Days -13 and -12 prior to the treatment start with cibisatamab on Cycle 1 Day 1.
Tocilizumab will be administered as an IV infusion as necessary to treat adverse events.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Cibisatamab, obinutuzumab, tocilizumab

Primary outcome measure
1. Percentage of participants with adverse events (AEs) or serious adverse events (SAEs) measured using National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v4.03 (NCI CTCAE v5 was used for CRS) at baseline up to 60 months
2. Percentage of participants with dose-limiting toxicities (DLTs) measured using NCI CTCAE v4.03 (NCI CTCAE v5 was used for CRS) at Day 1 up to Day 21
3. Percentage of participants with anti-drug antibodies (ADAs) against cibisatamab measured using an ADA assay at pre-dose (Hour 0) on Cycle 1 Day 1 up to 60 months (detailed timeframe is provided in the outcome description section)]
Part I: Pre-dose (Hour 0) on Day 1 of Cycles 1, 2-3; 120 hours after the end of infusion (EOI) in Cycle 1. Part II QW: pre-dose (Hour 0) on Day 1 of Cycles 1, 2, 3, 4. Part II Q3W: pre-dose (Hour 0) on Day 1 of Cycles 1, 2, 3, 4; 120 hours and 336 hours after EOI in Cycle 1, and 120 hours after EOI in Cycles 2, 3, 4. For Part I and II (QW and Q3W): pre-dose (Hour 0) on Day 1 of every cycle after Cycle 4 (Cycle 3 for Part I) up to treatment discontinuation (approximately 60 months), 28 days after last dose (approximately 60 months) (Cycle = 7 days for Part I and II QW; 21 days for Part II Q3W) (infusion duration = 30 minutes for Part I and 120 minutes for Part II [QW and Q3W])
4. MTD of cibisatamab with/without obinutuzumab pretreatment measured using NCI CTCAE v4.03 (NCI CTCAE v5 was used for CRS) at Day 1 up to Day 21
5. Late cycle MTD of cibisatamab without obinutuzumab pretreatment for the step-up dosing regimen measured using NCI CTCAE v4.03 (NCI CTCAE v5 was used for CRS) at Day 1 up to Day 7 of each cycle as long as the dose is escalated weekly in Part II QW (up to approximately 60 months; Cycle = 7 days)]. Late cycle MTD is defined as the highest dose with less than or equal to DLT having been observed for 6 evaluable participants. If more than 6 participants are evaluable for DLT, late-cycle MTD is the highest dose where less than (<) 33% of participants have DLT.
6. Maximum serum concentration (Cmax) for cibisatamab measured using a validated bi-functional pharmacokinetic (PK) assay at pre-dose (Hour 0) on Cycle 1 Day 1 up to 60 months (detailed timeframe is provided in the outcome description section)]
Part I: Pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2-3; 24, 48, and 120 hours after EOI of Cycle 1. Part II QW: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24 and 120 hours after EOI of Cycles 1 and 2; 48 hours after EOI of Cycle 1. Part II Q3W: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24, 48, 120, and 336

hours after EOI of Cycle 1; 24 and 120 hours after EOI of Cycles 2, 3, and 4; 48 hours after EOI of Cycle 2. For Part I and II (QW and Q3W): pre-dose (Hour 0), EOI, 2 hours after EOI (only for Part I) on Day 1 of every cycle after Cycle 4 (Cycle 3 for Part I), 2 hours after EOI on Day 1 of Cycles 8 and 12 (only for Part II QW) up to treatment discontinuation (approximately 60 months), 28 days after last dose (approximately 60 months) (Cycle =7 days for Part I and II QW; 21 days for Part II Q3W) (infusion duration = 30 minutes for Part I and 120 minutes for Part II [QW and Q3W])
7. Area under the concentration-time curve (AUC) for cibisatamab measured using a validated bi-functional PK assay at pre-dose (Hour 0) on Cycle 1 Day 1 up to 60 months (detailed timeframe is provided in the outcome description section)]
Part I: Pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2-3; 24, 48, and 120 hours after EOI of Cycle 1. Part II QW: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24 and 120 hours after EOI of Cycles 1 and 2; 48 hours after EOI of Cycle 1. Part II Q3W: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24, 48, 120, and 336 hours after EOI of Cycle 1; 24 and 120 hours after EOI of Cycles 2, 3, and 4; 48 hours after EOI of Cycle 2. For Part I and II (QW and Q3W): pre-dose (Hour 0), EOI, 2 hours after EOI (only for Part I) on Day 1 of every cycle after Cycle 4 (Cycle 3 for Part I), 2 hours after EOI on Day 1 of Cycles 8 and 12 (only for Part II QW) up to treatment discontinuation (approximately 60 months), 28 days after last dose (approximately 60 months) (Cycle =7 days for Part I and II QW; 21 days for Part II Q3W) (infusion duration = 30 minutes for Part I and 120 minutes for Part II [QW and Q3W])
8. Half-life (t1/2) of cibisatamab measured using a validated bi-functional PK assay at pre-dose (Hour 0) on Cycle 1 Day 1 up to 60 months (detailed timeframe is provided in the outcome description section)]
Part I: Pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2-3; 24, 48, and 120 hours after EOI of Cycle 1. Part II QW: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24 and 120 hours after EOI of Cycles 1 and 2; 48 hours after EOI of Cycle 1. Part II Q3W: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24, 48, 120, and 336 hours after EOI of Cycle 1; 24 and 120 hours after EOI of Cycles 2, 3, and 4; 48 hours after EOI of Cycle 2. For Part I and II (QW and Q3W): pre-dose (Hour 0), EOI, 2 hours after EOI (only for Part I) on Day 1 of every cycle after Cycle 4 (Cycle 3 for Part I), 2 hours after EOI on Day 1 of Cycles 8 and 12 (only for Part II QW) up to treatment discontinuation (approximately 60 months), 28 days after last dose (approximately 60 months) (Cycle =7 days for Part I and II QW; 21 days for Part II Q3W) (infusion duration = 30 minutes for Part I and 120 minutes for Part II [QW and Q3W])
9. Clearance (CL) of cibisatamab measured using a validated bi-functional PK assay at pre-dose (Hour 0) on Cycle 1 Day 1 up to 60 months (detailed timeframe is provided in the outcome description section)]
Part I: Pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2-3; 24, 48, and 120 hours after EOI of Cycle 1. Part II QW: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24 and 120 hours after EOI of Cycles 1 and 2; 48 hours after EOI of Cycle 1. Part II Q3W: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24, 48, 120, and 336 hours after EOI of Cycle 1; 24 and 120 hours after EOI of Cycles 2, 3, and 4; 48 hours after EOI of Cycle 2. For Part I and II (QW and Q3W): pre-dose (Hour 0), EOI, 2 hours after EOI (only for Part I) on Day 1 of every cycle after Cycle 4 (Cycle 3 for Part I), 2 hours after EOI on Day 1 of Cycles 8 and 12 (only for Part II QW) up to treatment discontinuation (approximately 60 months), 28 days after last dose (approximately 60 months) (Cycle =7 days for Part I and II QW; 21 days for Part II Q3W) (infusion duration = 30 minutes for Part I and 120 minutes for Part II [QW and Q3W])
10. Volume of distribution at steady state (Vss) of cibisatamab measured using a validated bi-functional PK assay at pre-dose (Hour 0) on Cycle 1 Day 1 up to 60 months (detailed timeframe is provided in the outcome description section)]
Part I: Pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2-3; 24, 48, and 120 hours after EOI of Cycle 1. Part II QW: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24 and 120 hours after EOI of Cycles 1 and 2; 48 hours after EOI of Cycle 1. Part II Q3W: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24, 48, 120, and 336

hours after EOI of Cycle 1; 24 and 120 hours after EOI of Cycles 2, 3, and 4; 48 hours after EOI of Cycle 2. For Part I and II (QW and Q3W): pre-dose (Hour 0), EOI, 2 hours after EOI (only for Part I) on Day 1 of every cycle after Cycle 4 (Cycle 3 for Part I), 2 hours after EOI on Day 1 of Cycles 8 and 12 (only for Part II QW) up to treatment discontinuation (approximately 60 months), 28 days after last dose (approximately 60 months) (Cycle =7 days for Part I and II QW; 21 days for Part II Q3W) (infusion duration = 30 minutes for Part I and 120 minutes for Part II [QW and Q3W])
11. Minimum drug concentration (Cmin) for cibisatamab measured using a validated bi-functional PK assay at pre-dose (Hour 0) on Cycle 1 Day 1 up to 60 months (detailed timeframe is provided in the outcome description section)]
Part I: Pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2-3; 24, 48, and 120 hours after EOI of Cycle 1. Part II QW: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24 and 120 hours after EOI of Cycles 1 and 2; 48 hours after EOI of Cycle 1. Part II Q3W: pre-dose (Hour 0), EOI, 2 hours after EOI on Day 1 of Cycles 1, 2, 3, and 4; 24, 48, 120, and 336 hours after EOI of Cycle 1; 24 and 120 hours after EOI of Cycles 2, 3, and 4; 48 hours after EOI of Cycle 2. For Part I and II (QW and Q3W): pre-dose (Hour 0), EOI, 2 hours after EOI (only for Part I) on Day 1 of every cycle after Cycle 4 (Cycle 3 for Part I), 2 hours after EOI on Day 1 of Cycles 8 and 12 (only for Part II QW) up to treatment discontinuation (approximately 60 months), 28 days after last dose (approximately 60 months) (Cycle =7 days for Part I and II QW; 21 days for Part II Q3W) (infusion duration = 30 minutes for Part I and 120 minutes for Part II [QW and Q3W])

Secondary outcome measures

1. Percentage of participants with an objective response of complete response (CR) or partial response (PR) measured using Response Evaluation Criteria in Solid Tumors (RECIST) Version (v) 1.1 at baseline up to 60 months (detailed timeframe is provided in the outcome description section)]
Baseline up to 60 months (assessed at Screening, at 12 weeks [in Part I], at 8 weeks [in Part II QW and Q3W] after Cycle 1 Day 1, every 8 weeks for the first 12 months, thereafter every 12 weeks until disease progression or death whichever occurs first, up to 60 months) (Cycle = 7 days for Part I and II QW, and 21 days for Part II Q3W)
2. Duration of response (DOR) measured using RECIST v1.1 at baseline up to 60 months (detailed timeframe is provided in the outcome description section)]
Baseline up to 60 months (assessed at Screening, at 12 weeks [in Part I], at 8 weeks [in Part II QW and Q3W] after Cycle 1 Day 1, every 8 weeks for the first 12 months, thereafter every 12 weeks until disease progression or death whichever occurs first, up to 60 months) (Cycle = 7 days for Part I and II QW, and 21 days for Part II Q3W)
3. Percentage of participants with stable disease (SD) measured using RECIST v1.1 at baseline up to 60 months (detailed timeframe is provided in the outcome description section)]
Baseline up to 60 months (assessed at Screening, at 12 weeks [in Part I], at 8 weeks [in Part II QW and Q3W] after Cycle 1 Day 1, every 8 weeks for the first 12 months, thereafter every 12 weeks until disease progression or death whichever occurs first, up to 60 months) (Cycle = 7 days for Part I and II QW, and 21 days for Part II Q3W)
4. Percentage of participants with disease control, defined as partial response + complete response + stable disease (PR+CR+SD), measured using RECIST v1.1 at baseline up to 60 months (detailed timeframe is provided in the outcome description section)]
Baseline up to 60 months (assessed at Screening, at 12 weeks [in Part I], at 8 weeks [in Part II QW and Q3W] after Cycle 1 Day 1, every 8 weeks for the first 12 months, thereafter every 12 weeks until disease progression or death whichever occurs first, up to 60 months) (Cycle = 7 days for Part I and II QW, and 21 days for Part II Q3W)
5. Progression-free survival (PFS) measured using RECIST v1.1 from the first study treatment to the first occurrence of objective disease progression or death from any cause (up to 60 months)
6. Best overall response (BOR) measured using RECIST v1.1 at baseline up to 60 months

(detailed timeframe is provided in the outcome description section)]
Baseline up to 60 months (assessed at Screening, at 12 weeks [in Part I], at 8 weeks [in Part II QW and Q3W] after Cycle 1 Day 1, every 8 weeks for the first 12 months, thereafter every 12 weeks until disease progression or death whichever occurs first, up to 60 months) (Cycle = 7 days for Part I and II QW, and 21 days for Part II Q3W)
7. Change from baseline in activated intra-tumoral cells measured using immunohistochemistry (IHC), gene expression and fluorescence-activated cell sorting (FACS) at baseline, Day 1 of Cycles 2, 3, 4, or 7 in Part II QW and Q3W (Cycle = 7 days for Part II QW and 21 days for Part II Q3W)]

Overall study start date
28/05/2014

Overall study end date
03/09/2019

Eligibility

Participant inclusion criteria
1. For dose escalation, locally advanced and/or metastatic gastrointestinal (GI) solid tumor in participants who have progressed on a standard therapy, are intolerant to SOC, and/or are non-amenable to SOC and other solid tumors expressing CEA. Only locally advanced and/or metastatic colorectal cancer participants should be included in the scheduled comparison expansion
2. Radiologically measurable disease according to RECIST v1.1
3. Life expectancy, in the opinion of the investigator of greater than or equal (>/=) to 12 weeks and LDH= 2.5 x ULN
4. Eastern Cooperative Oncology Group Performance Status of 0-1
5. All acute toxic effects of any prior radiotherapy, chemotherapy, or surgical procedure must have resolved to Grade less than or equal to 1 or returned to baseline except alopecia (any grade) and Grade 2 peripheral neuropathy
6. Adequate hematological, liver, and renal function
7. Participants must agree to remain abstinent or be willing to use effective methods of contraception as defined in the protocol
8. Non-GI solid tumors (like non-small cell lung cancer or breast cancer) should have confirmed CEA expression in tumor tissue >/= 20% of tumor cells staining with at least moderate to high intensity of CEA expression are required (immunohistochemistry [IHC]2+ and IHC 3+). For CRC, pancreatic and gastric cancer participants, the CEA assessment will be performed retrospectively and the result is not needed to enroll the participant

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
149

Total final enrolment
149

Participant exclusion criteria
1. Participants with a history or clinical evidence of central nervous system primary tumors or metastases including leptomeningeal metastases unless they have been previously treated, are asymptomatic, and have had no requirement for steroids or enzyme-inducing anticonvulsants in the last 14 days before screening
2. Spinal cord compression not definitively treated with surgery and/or radiation or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for at least 2 weeks prior to enrollment
3. Leptomeningeal disease
4. Participants with paraspinal, paratracheal and mediastinal pathologic lesions larger than 2 centimeters unless they are previously irradiated. Irradiation of lesions must be completed at least 14 days prior to initiation of study treatment
5. Participants with another invasive malignancy in the last 2 years (with the exception of basal cell carcinoma and tumors deemed by the investigator to be of low likelihood for recurrence)
6. Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results or contraindicate the use of an investigational drug, including diabetes mellitus, history of relevant cardio-pulmonary disorders, and known autoimmune diseases
7. Participants with bilateral lung lesions and dyspnea and/or with bilateral lung lesions and an oxygen saturation (SaO2) level less than 92% or participants with lobectomy or pneumonectomy with lung metastases in the remaining lung and either dyspnea or SaO2 less than 92% at baseline
8. Uncontrolled hypertension (systolic blood pressure [BP] greater than [>] 150 millimeters of mercury [mmHg] and/or diastolic BP > 100 mmHg), unstable angina, congestive heart failure of any New York Heart Association classification, serious cardiac arrhythmia that requires treatment with the exceptions of atrial fibrillation and paroxysmal supraventricular tachycardia, and history of myocardial infarction within 6 months of enrollment
9. Active or uncontrolled infections
10. Known human immunodeficiency virus (HIV) or known active hepatitis B or hepatitis C infection for participants not receiving obinutuzumab pretreatment
11. Known HIV (HIV testing will be performed at screening if required by local regulations) in participants to be pretreated with obinutuzumab
12. Pregnant or breastfeeding women
13. Known hypersensitivity to any of the components of cibisatamab and/or obinutuzumab
14. Concurrent therapy with any other investigational drug
15. Last dose of any chemotherapy less than 28 days prior to the first cibisatamab infusion
16. Expected need for regular immunosuppressive therapy
17. Regular dose of corticosteroids the 28 days prior to Day 1 of this study or anticipated need for corticosteroids that exceeds prednisone 10 mg/day or equivalent within 28 days prior to the first cibisatamab infusion. Inhaled and topical steroids are permitted
18. Radiotherapy within the last 28 days prior to the first cibisatamab infusion with the exception of limited-field palliative radiotherapy.
19. Additional Exclusion Criteria for Participants to be Pretreated with Obinutuzumab:
20. Positive test results for human T-lymphotropic virus 1 (HTLV-1) or active HIV infection
21. Positive test results for chronic hepatitis B infection or hepatitis C
22. Known active tuberculosis (TB) requiring treatment within 3 years prior to baseline or latent TB that has not been appropriately treated
23. Active bacterial, viral, fungal, or other infection, or any major episode of infection requiring treatment with intravenous (IV) antibiotics within 4 weeks of Cycle 1, Day 1

24. Known hypersensitivity to any of the components of obinutuzumab; hypersensitivity to Chinese hamster ovary cell products or other recombinant human antibodies
25. History of progressive multifocal leukoencephalopathy (PML)

Recruitment start date
30/12/2014

Recruitment end date
02/05/2018

Locations

Countries of recruitment
Canada

Denmark

Italy

Netherlands

Spain

United States of America

Study participating centre
Cedars Sinai Medical Center
Samuel-Oschin Comprehensive Cancer Institute
Los Angeles
United States of America
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Genentech

Alternative Name(s)
Genentech, Inc., Genentech USA, Inc., Genentech USA

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. No protocol/additional study documents will be made available.

Intention to publish date
30/11/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement for Phase I studies.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		27/08/2020	23/06/2021	No	No