A Phase 1/2, First-in-Human, Open-Label, Dose Escalation Study of Teclistamab, a Humanized BCMA x CD3 Bispecific Antibody, in Subjects with Relapsed or Refractory Multiple Myeloma.

Published: 21-06-2018
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This study has been transitioned to CTIS with ID 2023-503438-40-00 check the CTIS register for the current data. Primary: - Part 1 (Dose Escalation): To identify the recommended Phase 2 dose(s) and schedule assessed to be safe for teclistamab - Part...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Interventional

Summary

ID

NL-OMON56207

Source
ToetsingOnline

Brief title
MajesTEC-1

Condition

- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
Multiple Myeloma

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: door de opdrachtgever

Intervention

Keyword: Dose Escalation, Dose Expansion, JNJ-64007957, Multiple Myeloma

Outcome measures

Primary outcome

SAFETY EVALUATIONS

The safety of teclistamab will be assessed by physical examinations (including basic neurological assessment or Immune Effector Cell-associated Encephalopathy [ICE] Tool [Part 3], ECOG performance status, laboratory tests, vital signs, electrocardiograms, adverse event monitoring, and concomitant medication usage.

The severity of adverse events will be assessed using National Cancer Institute Common Terminology Criteria for Adverse Events (NCI NCTAE; Version 4.03), except as follows:

• In Part 1 and Part 2, CRS will be graded according to a CRS revised grading system. In Part 3, CRS will be graded according to the American Society for Transplantation and Cellular Therapy (ASTCT) grading system.

• Neurological adverse events will be graded based on NCI CTCAE Version 4.03 in all Parts of the study. Additionally, in Part 3, an ICE score and ASTCT grade will also be collected for immune effector cell-associated neurotoxicity syndrome (ICANS) events.

CRS has been identified as an adverse event of special interest and will require enhanced reporting and data collection for all Parts of the study.

Neurotoxicity events Grade >=2 have been identified as an adverse event of special interest for Part 3.

PHARMACOKINETIC AND IMMUNOGENICITY EVALUATIONS

Blood samples will be collected from all subjects for the measurement of serum teclistamab concentration for pharmacokinetic analyses. Pharmacokinetic parameters will be determined after the first dose at Cycle 1 and the first dose at Cycle 3 for Part 1 and Part 2. Exploratory population pharmacokinetic-based approach may also be applied for the pharmacokinetic analysis. The detection and characterization of antibodies to teclistamab will be performed using a validated assay method to enable interpretation of the anti-drug antibody data. In Part 3, teclistamab serum concentration will be used in a population pharmacokinetic and exposure-response analysis.

PHARMACODYNAMIC AND BIOMARKER EVALUATIONS

Biomarker assessments will focus on 3 main objectives:

1. evaluate the immune responses indicative of T cell redirection for potential contributions to teclistamab response;

2. determine the ability of teclistamab to achieve minimal residual disease (MRD) in subjects who have at least a CR; and

3. determine the clinical benefit of teclistamab in subjects with cytogenetic modifications or other high- risk molecular subtypes.

4. Samples will be collected to evaluate receptor occupancy (RO) in Part 1

and 2, to quantify the binding of therapeutics to their targets on the cell

surface.

Secondary outcome

Nap

Study description

Background summary

Multiple myeloma is a malignant plasma cell disorder characterized by production of monoclonal proteins (M-proteins) comprised of pathological immunoglobulins or fragments of such, which have lost their function. The proliferation of multiple myeloma cells leads to subsequent displacement from the normal bone marrow niche, while overproduction of M-protein causes characteristic hallmarks of multiple myeloma such as osteolytic lesions, increased susceptibility to infections, hypercalcemia, renal insufficiency or failure, and neurological complications. Despite recent major therapeutic improvements, the disease recurs and is associated with additional risk factors (eg, comorbidities or increasing age), thus warranting the need for novel therapeutic approaches.
In this regard, B cell (B lymphocyte) maturation antigen (BCMA, also known as CD269 and TNFRSF17) is a 20 kilodalton, type I membrane protein, which is part of the tumor necrosis receptor family. BCMA is predominantly expressed in B-lineage cells and selectively induced during plasma cell differentiation associated with the loss of B cell activating factor receptor (BAFF-R).
Moreover, in multiple myeloma cell lines and patient samples, BCMA is more stably expressed compared with CD138, a key plasma cell marker, thus making it an ideal therapeutic target.
Recently, several approaches were developed to redirect T lymphocytes (T cells) to tumor surface antigens leading to antitumor activity and clinical benefit for patients. Such approaches include the development of drugs which broke tumor tolerance by T cell exhaustion checkpoint blockade, including inhibition of cytotoxic T-lymphocyte-associated antigen-4 and programmed death-1. These results suggest that redirecting T cells to tumor surface antigens by using bispecific approaches may be an effective means to harness the immune system to cause cell death in cancer cells and to create meaningful and long-lasting clinical responses.
This is a Phase 1/2 study; Phase 1 includes Part 1 and Part 2, and the Phase 2 component is Part 3. This study will enroll subjects with relapsed or refractory multiple myeloma. Part 3 will enroll subjects in cohorts that differ by prior therapies. Cohort A and C will enroll first.

• Cohort A will enroll subjects with multiple myeloma who are triple class exposed (proteasome inhibitor [PI], immunomodulatory drug [IMiD], and an anti-CD38 monoclonal antibody) and have previously received treatment with >=3 prior lines of therapy.
• Cohort C will enroll subjects who have previously received >=3 prior lines of therapy that included a PI, an IMiD, an anti-CD38 monoclonal antibody, and an anti-BCMA treatment (chimeric antigen receptor [CAR]-T cells or an antibody drug conjugate [ADC]).

Study objective

This study has been transitioned to CTIS with ID 2023-503438-40-00 check the CTIS register for the current data.

Primary: - Part 1 (Dose Escalation): To identify the recommended Phase 2 dose(s) and schedule assessed to be safe for teclistamab - Part 2 (Dose Expansion): To characterize the safety and tolerability of teclistamab at the recommended Phase 2 dose(s) (RP2Ds) - Part 3 (Phase 2): To evaluate the efficacy of teclistamab at the RP2D Secondary: Part 1&2 -To characterize the pharmacokinetics and pharmacodynamics of teclistamab - To evaluate the preliminary antitumor activity of teclistamab at the RP2D(s) in Part 2 Part 3 - To further assess the efficacy of teclistamab at the RP2D - To evaluate MRD at the RP2D - To further assess the safety and tolerability of teclistamab at the RP2D

Study design

This is a first-in-human (FIH), Phase 1/2, open-label, multicenter dose escalation study with dose expansion to identify the RP2D and to evaluate the safety, tolerability, pharmacokinetics, and anti-myeloma activity of teclistamab (also known as JNJ-64007957) administered to adult subjects with relapsed or refractory multiple myeloma. The overall safety of the study drug will be assessed by the Safety Evaluation Team (SET) in Part 1 and Part 2.
The study will be conducted in 3 parts: dose escalation (Part 1), dose expansion at proposed RP2Ds (Part 2), and Phase 2 dose expansion in cohorts of subjects with relapsed or refractory multiple myeloma with unmet medical need (Part 3).
The study was initiated with a biweekly (ie, every 2 weeks [Q2W]) IV dosing schedule. A weekly IV dosing schedule was initiated by the sponsor after review of emerging safety and pharmacokinetic data from the Q2W IV dosing schedule showed subjects may not have sufficient teclistamab exposure beyond Day 8 following the first dose. A weekly SC dosing schedule was also initiated. Based on emerging safety and pharmacokinetic data, the SET may propose alternative dosing; schedules such as monthly dosing or gradual extension of the dosing interval from weekly to biweekly to monthly may also be explored. Variations on dosing, including bracketing by weight and fixed dosing, have also been

evaluated in Part 1 1; these subjects will be transitioned to weight-based dosing following imlememtnation of Amendment
14..
Following Amendment 13, a Part 1 cohort will be added that will receive teclistamab derived from a new drug substance manufacturing process.
Part 1
Biweekly (Q2W) dosing cohorts:
Dose escalation using IV administration began at the starting dose level of 0.3 µg/kg and the subsequent dose levels were selected based on a statistical model and using all available data to identify safe and tolerable proposed RP2D(s).
Weekly dosing cohorts:
Dose escalation for both IV and SC administration began at a cleared dose level approved by the Safety Evaluation Team (SET), and the subsequent dose levels are being selected based on a statistical model and using all available data to identify safe and tolerable proposed RP2D(s).
The total number of subjects treated in Part 1 will depend on the number of dose levels explored and the number of subjects enrolled at each dose level. In Part 1 the sample size for IV administration is
approximately 100 subjects, with SC dosing enrolling approximately 150 additional subjects. A staggered enrollment strategy will be applied. For each dose level, a minimum interval of 72 hours after the first dose for the first subject is required in the accelerated titration phase.

Exploratory cohorts may also be added in Part 1 to investigate administration of tocilizumab as a pretreatment medication or low-dose dexamethasone given daily during priming and early in Cycle 1.

Subjects treated with IV administration will be hospitalized for at least 36 hours from the start of any priming doses and the start of the first full dose of study drug, and at least 24 hours from the start of the second full dose of study drug. Hospitalization requirements may be modified by the SET based on all available data, including safety, pharmacokinetics, and pharmacodynamics.
Subjects treated in the initial cohort for SC administration will be hospitalized for at least 48 hours from the start of any priming injection of study drug and from the start of the first full injection of study drug, and at least 24 hours from the start of the second full injection of study drug. The duration or need for hospitalization after SC administration for further cohorts will be determined by the SET based on all available data including safety, pharmacokinetics, and pharmacodynamics.
Part 2
In Part 2 (dose expansion), the proposed RP2D(s) will be further explored and up to 40 subjects may receive teclistamab at the proposed RP2D(s) determined in Part 1 to further characterize preliminary antitumor activity and safety in additional subjects at the relevant dose(s).
Part 3
Enrollment for Part 3 will begin after at least 20 subjects have been treated with SC teclistamab at 1500 µg/kg for at least 1 cycle. The sponsor may also

determine that additional subjects are required to further evaluate safety and dose prior to proceeding to Part 3.Cohort B will not enroll.
All Parts
Disease evaluations; including peripheral blood; 24-hour urine collections, bone marrow samples, and imaging as applicable; will be performed per IMWG. Disease status will be evaluated according to the IMWG consensus recommendations for multiple myeloma treatment response criteria.
Subjects will continue to receive study drug until disease progression, unacceptable toxicity, withdrawal of consent, death, or end of study defined as 2 years after the last subject*s first dose. The sponsor will ensure that subjects who continue to benefit from treatment with study drug will be able to continue treatment after the end of the study per local regulations.

Intervention

There are several treatment schedules included in this study; the schedule you follow depends on when you are enrolled in the study. Your doctor will explain to you which schedule you are receiving. Treatment is given on what is known as a *cycle*. The duration of the cycle depends on the treatment schedule. You may receive the drug via an intravenous infusion (by vein) or via a subcutaneous injection (under the skin).

Dose Schedules:
- Study drug may be given on a weekly, bi-weekly or monthly schedule. Subcutaneous dosing will begin on a weekly schedule, but bi-weekly or dosing may be explored. If you receive study drug on a weekly subcutaneous schedule, you will be informed if your subcutaneous dosing schedule will change.
- If you are on the weekly IV or SC dose schedule, treatment will be given 3 times in a 21-day cycle. This means that you will receive study drug on Days 1, 8 and 15 of each 21-day cycle.
- If you are on the bi-weekly or monthly IV or SC dose schedule, treatment will be given 2 times in a 28-day cycle. This means that you will receive study drug on Days 1 and 15 of each 28-day cycle. Day 15 is not applicable for the monthly schedule

Hospitalization and Observation Requirements after study drug administration:
Weekly Dose Schedule:
- Cycle 1 Day 1; you will be hospitalized for at least 36 hours (intravenous infusion) or 48 hours (subcutaneous injection) from the start of the infusion/injection.
- Cycle 1 Day 8; you will be hospitalized for at least 24 hours from the start of the infusion/injection.
- For Cycle 1 Day 15 and Cycle 2 Day 1, you will remain at the site for observation for at least 2 hours (intravenous infusion) or 4 hours (subcutaneous injection). For subsequent infusions/injections you may be released from the site after being evaluated by study site staff.

Biweekly/Monthly Dose Schedule
- Cycle 1 Day 1; you will be hospitalized for at least 36 hours (intravenous infusion) or 48 hours (subcutaneous injection) from the start of the infusion/injection.
- Cycle 1 Day 15; you will be hospitalized for at least 24 hours from the start of the infusion/injection.
- For Cycle 2, you will remain at the site for at least 2 hours after the infusion/injection for observation. For subsequent infusions/injections you may be released from the site after being evaluated by study site staff

If you have side effects, you may need to be hospitalized after other infusions/injections.
The duration of hospitalization may change after all available data are reviewed. You will be informed if the length of hospitalization will change.

Priming Doses
You may receive one or more priming doses before the first full dose of study drug is given on Cycle 1 Day 1 of the weekly, bi-weekly or monthly schedules above. Priming doses are given at lower doses (not necessarily the same dose) and subsequent doses are given at a higher level.

If you receive the study drug intravenously, you will be hospitalized for at least 36 hours from the start of each priming infusion. This is in addition to the hospitalization requirements required for Cycle 1 infusions in the dose schedules above.

If you receive the drug subcutaneously you will be hospitalized for at least 48 hours from the start each priming injection. This is in addition to the hospitalization requirements required for Cycle 1 injections in the dose schedules above.

Part 3:
Priming Doses
You will receive 2 priming doses in the week before the first full dose of study drug is given. Priming doses are given at lower doses than the full treatment dose to manage side effects (see Risks section below). You will be hospitalized for at least 48 hours from the start of each priming dose.

Full Doses
After the priming doses are completed, teclistamab will be given 4 times in a 28-day cycle. This means that you will receive study drug on Days 1, 8, 15 and 22 of each 28-day cycle. The number of teclistamab doses you will receive is unknown as it will depend on how you respond to treatment. You will be hospitalized for at least 48 hours from the start of the first full dose on Cycle 1 Day 1. For doses after Cycle 1 Day 1 you may leave the site after being evaluated by study site staff. If you have side effects, you may need to be hospitalized after other doses.

The duration of hospitalization may change after all available data are reviewed. You will be informed if the length of hospitalization will change.

Pre- treatment medications
You will receive pre-treatment medications before each priming dose and before the first full dose on Cycle 1 Day 1. You will receive pre-treatment medications before teclistamab doses during other cycles if you have certain side effects or your investigator thinks it is needed.

Study burden and risks

Multiple myeloma is a malignant plasma cell disorder characterized by production of monoclonal proteins (M-proteins) comprised of pathological immunoglobulins or fragments of such, which have lost their function. The proliferation of multiple myeloma cells leads to subsequent displacement from the normal bone marrow niche, while overproduction of M-protein causes characteristic hallmarks of multiple myeloma such as osteolytic lesions, increased susceptibility to infections, hypercalcemia, renal insufficiency or failure, and neurological complications. Despite recent major therapeutic improvements, the disease recurs and is associated with additional risk factors (eg, comorbidities or increasing age), thus warranting the need for novel therapeutic approaches.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. >=18 years of age. 2. Documented diagnosis of multiple myeloma according to IMWG diagnostic criteria 3. Part 1 and Part 2: Measurable multiple myeloma that is relapsed or refractory to established therapies with known clinical benefit in relapsed/refractory multiple myeloma or be intolerant of those established multiple myeloma therapies, and a candidate for teclistamab treatment in the opinion of the treating physician. Prior lines of therapy must include a PI an IMiD and an anti-CD38 monoclonal antibody in any order during the course of treatment. Subjects who could not tolerate a PI, IMiD or an anti-CD38 monoclonal antibody are allowed. In Part 2 (dose expansion), in addition to above criteria, multiple myeloma must be measurable per current IMWG published guidelines by central lab assessment. If central lab assessment is not available, relevant local measurement must exceed the minimum required level by at least 25%. Part 3 Measurable disease Cohort A, Cohort C: Multiple myeloma must be measurable by central laboratory assessment: • Serum monoclonal paraprotein (M-protein) level >=1.0 g/dL or urine M-protein level >=200 mg/24 hours; or • Light chain multiple myeloma without measurable disease in the serum or the urine: Serum immunoglobulin free light chain (FLC) >=10 mg/dL and abnormal serum immunoglobulin kappa lambda FLC ratio. Prior treatment * Cohort A: Subjects must have 1) received >=3 prior lines of therapy and 2) previously received a PI, an IMiD, and an anti-CD38 monoclonal antibody. * Cohort C: received >=3 prior lines of therapy that included a PI, an IMiD, an anti-CD38 monoclonal antibody, and an anti-BCMA treatment (with CAR-T cells or an ADC). 4. Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0 or 1, 5.Pretreatment clinical laboratory values meeting the incl criteria, 6.A female subject of childbearing potential must have a negative pregnancy test at screening and prior to the first dose of study drug using a highly sensitive pregnancy test either serum (β human chorionic gonadotropin [β-hCG]) or urine., 7. Female subjects of childbearing potential and fertile male subjects who are sexually active must agree to use a highly effective method of contraception (<1%/year failure rate). Contraception must begin from the time of signing the ICF, continue during the study treatment, including during dose interruptions, and through 6 months and 3 months after the last dose of study drug, for female

and male subjects, respectively. Contraception must be consistent with local regulations regarding the use of birth control methods for subjects participating in clinical trials. 8. Subject must sign an informed consent form (ICF) indicating that he or she understands the purpose of and procedures required for the study and is willing to participate in the study. Consent is to be obtained prior to the initiation of any study-related tests or procedures that are not part of standard-of-care for the subject*s disease., 9. Willing and able to adhere to the prohibitions and restrictions specified in this protocol.

Exclusion criteria

1. Prior treatment with any BCMA targeted therapy, with the exception of Cohort C in Part 3. 2.Prior antitumor therapy as follows, before the first dose of study drug: * Targeted therapy, epigenetic therapy, or treatment with an investigational drug or used an invasive investigational medical device within 21 days or at least 5 half-lives, whichever is less. * Monoclonal antibody treatment for multiple myeloma within 21 days. * Cytotoxic therapy within 21 days. * Proteasome inhibitor therapy within 14 days. * Immunomodulatory agent therapy within 7 days. * Gene modified adoptive cell therapy (eg, chimeric antigen receptor modified T cells, natural killer [NK] cells) within 3 months. * Radiotherapy within 14 days or focal radiation within 7 days, 3. Toxicities from previous anticancer therapies that have not resolved to baseline levels or to Grade 1 or less except for alopecia or peripheral neuropathy., 4. Received a cumulative dose of corticosteroids equivalent to >=140 mg of prednisone within the 14-day period before the first dose of study drug (does not include pretreatment medication)., 5. Stem cell transplantation: * An allogeneic stem cell transplant within 6 months. Subjects who received an allogeneic transplant must be off all immunosuppresive medications for 6 weeks without signs of graft-versus-host disease. * Received an autologous stem cell transplant <=12 weeks before the first dose of study drug, 6. Known active CNS involvement or exhibits clinical signs of meningeal involvement of multiple myeloma., 7. Plasma cell leukemia (>2.0 x 109/L plasma cells by standard differential), Waldenstro*m*s macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), or primary amyloid light-chain amyloidosis., 8. Known to be seropositive for human immunodeficiency virus or acquired immune deficiency syndrome, 9.Hepatitis B infection or at risk for hepatitis B virus reactivation as defined according to the American Society of Clinical Oncology guidelines. Eligibilty will be determined by the investigator as described in the protocol. In the event the infection status is unclear, quantitative levels are necessary to determine the infection status. Active Hepatitis C infection as measured by positive hepatitis C virus (HCV)-RNA testing, in subjects with positive anti-HCV antibody or subjects with a history of HCV antibody positivity ., 10. Pulmonary compromise requiring supplemental oxygen use to maintain adequate oxygenation.,

11. Known allergies, hypersensitivity, or intolerance to the study drug (teclistamb) or its excipients (refer to Investigator*s Brochure), 12. Any serious underlying medical condition, such as: * Evidence of serious active viral, bacterial, or uncontrolled systemic fungal infection * Active autoimmune disease or a documented history of autoimmune disease with the exception of vitiligo, type I diabetes, and prior autoimmune thyroiditis that is currently euthyroid based on clinical symptoms and laboratory testing * Psychiatric conditions (eg, alcohol or drug abuse), dementia, or altered mental status * Stroke, seizure e or transient ischemic attack within 6 months of signing ICF. * Any other issue that would impair the ability of the subject to receive or tolerate the planned treatment at the investigational site, to understand informed consent or any condition for which, in the opinion of the investigator, participation would not be in the best interest of the subject (eg, compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments., 13. Pregnant or breast-feeding, or planning to become pregnant while enrolled in this study or within 6 months after receiving the last dose of study drug., 14. Plans to father a child while enrolled in this study or within 3months after receiving the last dose of study drug., 15. Major surgery within 2 weeks of the first dose, or will not have fully recovered from surgery, or has surgery planned during the time the subject is expected to participate in the study or within 2 weeks after the last dose of study drug administration. 16. The following cardiac conditions: • New York Heart Association stage III or IV congestive heart failure • Myocardial infarction or coronary artery bypass graft (CABG) <=6 months prior to enrollment • History of clinically significant ventricular arrhythmia or unexplained syncope, not believed to be vasovagal in nature or due to dehydration • History of severe non-ischemic cardiomyopathy 17. Myelodysplastic syndrome or active malignancies (ie, progressing or requiring treatment change in the last 24 months) other than the relapsed/refractory multiple myeloma. The only allowed exceptions are: • Non-muscle invasive bladder cancer treated within the last 24 months that is considered completely cured. • Skin cancer (non-melanoma or melanoma) treated within the last 24 months that is considered completely cured. • Noninvasive cervical cancer treated within the last 24 months that is considered completely cured. • Localized prostate cancer (N0M0): o With a Gleason score of 6, treated within the last 24 months or untreated and under surveillance. o With a Gleason score of 3+4 that has been treated more than 6 months prior to full study screening and considered to have a very low risk of recurrence, o Or history of localized prostate cancer and receiving androgen deprivation therapy and considered to have a very low risk of recurrence. • Breast cancer: o Adequately treated lobular carcinoma in situ or ductal carcinoma in situ, o Or history of localized breast cancer and receiving antihormonal agents and considered to have a very low risk of recurrence. • Malignancy that is considered cured with minimal risk of recurrence. 18. Live, attenuated vaccine within 4 weeks prior to the first dose of teclistamab.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-01-2019
Enrollment:	44
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Teclistamab
Generic name:	NAP

Ethics review

Approved WMO Date:	21-06-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-01-2019
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2020
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2021
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-03-2022
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-07-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-12-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-03-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-03-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2023
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-08-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-11-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-03-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	03145181
EU-CTR	CTIS2023-503438-40-00
EudraCT	EUCTR2016-002122-36-NL
CCMO	NL66216.029.18