An Open Label, Dose-Finding and Proof of Concept Study of the PD-L1 Probody* Therapeutic, CX-072, as Monotherapy and in Combination with Yervoy® (Ipilimumab) or with Zelboraf® (Vemurafenib) in Subjects with Advanced or Recurrent Solid Tumors or Lymphomas

Published: 03-01-2017
Last updated: 31-12-2024

The primary objectives of the study are:For Parts A through C:1. Evaluate the safety and tolerability of multiple doses of CX-072, administered as monotherapy or in combination with ipilimumab or vemurafenib to patients with metastatic or locally…

Ethical review	Approved WMO
Status	Completed
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON47426

Source
ToetsingOnline

Brief title
PROCLAIM-001

Condition

- Leukaemias

Synonym
advanced or recurrent solid tumors or lymphomas

Research involving
Human

Sponsors and support

Primary sponsor: CytomX Therapeutics
Source(s) of monetary or material Support: CytomX Therapeutics;Inc.

Intervention

Keyword: advanced or recurrent solid tumors or lymphomas, CX-072, Probody

Outcome measures

Primary outcome

1. Evaluate the safety and tolerability of multiple doses of CX-072,

administered as monotherapy or in combination with ipilimumab or vemurafenib to

subjects with metastatic or locally advanced unresectable solid tumors or

lymphomas.

2. Determine the maximum tolerated dose (MTD) and dose limiting toxicities

(DLTs) of:

• CX-072 as a monotherapy administered to PD-1/PD-L1 naïve subjects,

• CX-072 in combination with ipilimumab (concomitant schedule) administered to

PD-1/PD-L1 and CTLA-4 inhibitor naïve subjects,

• CX-072 in combination with ipilimumab (phased schedule) administered to

subjects that have had prior treatment with a PD-1/PD-L1 inhibitor, and

• CX-072 in combination with vemurafenib administered to PD-1/PD-L1 naïve

subjects.

Substudy:

Whole body 89Zr-CX-072 distribution

Secondary outcome

1. Obtain preliminary evidence of anti-cancer activity on the basis of objective responses in subjects treated with CX-072 as monotherapy or when administered in combination with ipilimumab or vemurafenib:

• Objective response rate by the Response Evaluation Criteria in Solid Tumors (RECIST 1.1 and irRECIST),

• Objective response rate by modified immune-related response criteria as defined in the Common Core Document or Modified Cheson/Lugano Classification for Lymphomas,

• Time to response (TTR)

• Duration of response (DOR)

• Progression-free survival (PFS)

Obtain preliminary evidence of anti-cancer activity on the basis of objective responses in subjects treated with CX-072 as monotherapy in advanced or metastatic gastric and undifferentiated pleomorphic sarcoma (UPS) tumors

2. Characterize the incidence of anti-drug antibodies (ADA) against CX-072 and ipilimumab

3. Characterize the single and multi-dose pharmacokinetic profile of CX-072 when administered alone, and CX-072, ipilimumab, and vemurafenib when administered in combination

4. Assess overall survival (OS) in subjects receiving CX-072

Substudy:

Tumor and immune cell PD-1 and PD-L1 expression analysis in a fresh baseline

biopsy, correlated to 89Zr-CX-072 tumor uptake

Study description

Background summary

Clinical trials have confirmed the capacity of PD-1/PD-L1 blockade to effectively restore the activity of tumor specific immunity, leading to responses in approximately 60% of subjects with advanced melanoma and approximately 20% of subjects across multiple additional tumor types (Herbst et al, 2014; Lipson et al, 2015).
CX-072 is directed against PD-L1 for the treatment of cancer and is the first under the CytomX Probody platform to be studied in humans.
In mouse models, a surrogate form of CX-072 is as efficacious as anti-PD-L1 antibodies, but demonstrates reduced binding to T cells outside of the tumor and induces less autoimmunity. CX-072 is designed to widen the therapeutic window by reducing interaction with PD-L1 in normal tissue environments while maintaining interaction with tumor tissue.

Substudy:
Radiolabeling of CX-072 with the PET radionuclide 89Zr enables serial non-invasive imaging and quantification of distribution of 89Zr-CX-072. By performing 89Zr-CX-072-PET scans prior to initiation of CX-072 treatment as part of the main study, whole body distribution and 89Zr-CX-072 can be evaluated and compared to treatment response and toxicity during treatment.

Study objective

The primary objectives of the study are:
For Parts A through C:
1. Evaluate the safety and tolerability of multiple doses of CX-072, administered as monotherapy or in combination with ipilimumab or vemurafenib to patients with metastatic or locally advanced unresectable solid tumors or lymphomas.
2. Determine the MTD and DLTs of:
- CX-072 as monotherapy administered to PD-1/PD-L1 naive patients,
- CX-072 in combination with Ipilimumab administered to PD-1/PD-L1 and CTLA-4 inhibitor naive patients,
- CX-072 in combination with Ipilimumab administered to patients that have had prior treatment with a PD-1/PD-L1 inhibitor, and
- CX-072 in combination with vemurafenib administered to PD-1/PD-L1 naive patients.

for Parts D and E: to obtain evidence of the efficacy of CX-072 monotherapy, respectively, via the ORR according to the RECIST v 1.1 (UPS, small bowel adenocarcinoma, cSCC, MCC, TET, anal SCC, TNBC with skin lesions, and hTMB [Part D]), as assessed by Investigator (Part D) or by independent review facility(Part E).

The secondary objectives of the study are:
Parts A-C:
1. Obtain preliminary evidence of anti-cancer activity on the basis of objective responses in patients treated with CX-072 as monotherapy or when administered in combination with ipilimumab or vemurafenib:
* Objective response rate by RECIST 1.1,
* Objective response rate by modified immune-related response criteria as defined in the Common Core Document or Modified Cheson/Lugano Classification for Lymphomas,
* Time to response (TR),
* Duration of response (DR), and
* Progression-free survival (PFS);

2.Characterize the incidence of ADAs against CX072 and ipilimumab;

3. Characterize the single and multi-dose pharmacokinetic profile of CX-072 when administered alone,
and CX-072,ipilimumab,vemurafenib when administered in combination;

4. Assess overall survival (OS) in subjects receiving CX-072.

Part:D-E:
1.Characterize the efficacy of CX-072 monotherapy by:
•DOR as assessed by Investigator (PartD) or by IRF(PartE)
•ORR by RECIST v1.1 by PD-L1 expression (PartE)
•ORR by modified irRECIST defined in the CommonCore
•PFS

2.Evaluate safety, tolerability of CX-072 administered as monotherapy
3.Characterize incidences of ADAs against CX-072
4.Characterize the PK profile of CX-072 5.OS in pts receiving CX-072

The exploratory objectives of the study are:
1. Examine the relationship between dose/exposure and PD, safety, and efficacy of CX-072 as monotherapy administered to subjects with PD-L1+ cancer;
2. Explore potential predictive markers associated with CX-072 clinical activity based on levels of expression of PD-L1 in tumor specimens prior to and while receiving treatment;
3. Characterize the protease activity and degree of CX-072 cleavage in tumor and peripheral blood; and
4. Investigate the immunomodulatory activity of CX-072 in on-treatment

biopsies; and
5.Perform an analysis of tumor mutation burden in subjects that respond to treatment in Part D.

Substudy:
The primary objective of this substudy is to evaluate the whole body distribution of Zr-CX-072 in subjects with locally advanced or metastatic solid tumors or malignant lymphoma.

Study design

The study is divided into 6 parts:
For Parts A through C:
• Part A: CX-072 monotherapy dose escalation
o Any metastatic or advanced unresectable solid tumor or lymphoma (n <= 33), measurable or non-measurable disease
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available for their specific disease in the country where they are being treated)
o CX-072 monotherapy (0.03, 0.1, 0.3, 1, 3, 10, 30 mg/kg) IV q14 days

• Part A2: CX-072 monotherapy dose effect
o Any metastatic or advanced unresectable solid tumor or lymphoma (at least 2 subjects in each cohort with thymic epithelial tumor, thymoma, or thymic carcinoma) (n <= 24), measurable disease, relapsed or refractory
o Tumor proportion score (TPS) >= 1% membranous staining based on the DAKO PD-L1 IHC 22C3 pharmDx
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available for their specific disease in the country where they are being treated)
o Participation in biomarker analysis and biopsies
o CX-072 monotherapy (0.3, 1, 3, and 10 mg/kg) IV q14 days
o Initiation of each cohort*s enrollment requires successful completion of the Part A CX-072 monotherapy at that dose level

• Part B1: CX-072 plus ipilimumab combination dose escalation (concomitant schedule)
o Any metastatic or advanced unresectable solid tumor or lymphoma (excluding thymic epithelial tumor, thymoma, or thymic carcinoma) (n <= 42), measurable or non-measurable disease
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available for their specific disease in the country where they are being treated)
o CX-072 (0.3, 1, 3, 10 mg/kg) in combination with ipilimumab (3, 6 or 10

mg/kg) IV q21 days × 4 doses in a concomitant schedule followed by CX-072 monotherapy IV q14 days
o Initiation of cohort enrollment requires successful completion of the subsequent CX-072 monotherapy dose level tested in Part A

• Part B2: CX-072 monotherapy run-in followed by CX-072 plus ipilimumab combination dose escalation (phased schedule)
o Any metastatic or advanced unresectable solid tumor or lymphoma (excluding thymic epithelial tumor, thymoma, or thymic carcinoma) (n <= 30), measurable disease
o Prior therapy with PD-1/PD-L1 inhibitors, discontinued for reasons other than toxicity
o CTLA-4 inhibitor naive
o CX-072 monotherapy run in (3, 10 mg/kg) IV q14 days × 4 doses followed by CX-072 plus ipilimumab combination (3, 6 or 10 mg/kg) IV q21 days × 4 doses; followed by CX-072 monotherapy IV q14 days
o Initiation of cohort enrollment requires successful completion of the subsequent CX-072 monotherapy dose level tested in Part A
o Participation in biomarker analysis and biopsies (only in cohorts receiving CX-072 + 3 mg/kg ipilimumab [but not 6 or 10 mg/kg ipilimumab])

• Part C: CX-072 plus vemurafenib combination dose escalation
o BRAF V600E mutation-positive metastatic or advanced unresectable melanoma (n <= 24), measurable or non-measurable disease
o BRAF-inhibitor naive
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available for their specific disease in the country where they are being treated)
o CX-072 (1, 3, 10 mg/kg) IV q14 days in combination with vemurafenib 960 mg PO twice daily (approximately every 12 hours), concomitant schedule
o Initiation of cohort enrollment requires successful completion of the subsequent CX-072 monotherapy dose level tested in Part A

• Part D: Expansion cohort for safety and efficacy at doses up to the CX-072 monotherapy MTD/MAD
o Metastatic or advanced unresectable undifferentiated pleomorphic sarcoma (UPS) (n <= 20), small bowel adenocarcinoma (n <= 25), cutaneous squamous cell carcinoma (cSCC) (n <= 25), triple negative breast cancer (TNBC) (n <= 25), and high tumor mutational burden (hTMB) (n <= 25) measurable disease
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available for their specific disease in the country where they are being treated)
o CX-072 monotherapy at doses up to the MTD/MAD
o TPS >= 1% membranous staining or unknown PD-L1 status
o Subjects must have had standard of care surgery and/or radiation for their

UPS; subjects with metastatic disease should have received at least 1 prior systemic therapy according to local guidelines

Substudy:
The substudy is divided into 2 parts, I-1 and I-2.
Up to 3 cohorts of 2 to 3 subjects each will enroll in Part I-1. All subjects in this part will receive the same fixed dose of 37 MBq 89Zr-CX-072 and will undergo 1 89Zr-CX-072-PET scan per day on Days 2, and 7 following 89Zr-CX-072 administration.
Once the optimal dose of unlabeled CX-072 to be given in combination with 89Zr-CX-072 and the optimal timing between Zr-CX-072 administration and PET-imaging are determined, Part I-2 will open.
Ten to 12 eligible subjects will undergo 89Zr-CX-072-PET imaging.

Intervention

Patients will receive either CX-072, CX-072 in combination with ipilimumab or CX-072 in combination with vemurafenib

Substudy:
Patients will receive 89Zr-CX-072 either alone or in combination with unlabeled CX-072

Study burden and risks

Risks: possible side effects of the study medications

Burden:study procedures such as blood draws, CT/PET or MRI scans, bonescans and biopsies (depending on study group)

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

All pts must have histologically confirmed diagnosis of metastatic or locally advanced unresectable tumors that progressed or are intolerant to standard therapy.
Inclusion criteria for subjects in each specific Part: ;• Part A: any metastatic or advanced unresectable solid tumor or lymphoma, measurable or nonmeasurable disease allowed, no further SOC therapy available;
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available for their specific disease in the country where they are being treated); and
o Subjects participating in the imaging substudy must meet both main study and substudy entry criteria to be enrolled in the study; ;• Part A2: any metastatic or advanced unresectable solid tumor or lymphoma (at least 2 subjects in each cohort with thymic epithelial tumor, thymoma, or thymic carcinoma), measurable disease allowed, no further SOC therapy available;
o TPS >= 1% membranous staining based on the DAKO PD-L1 IHC 22C3 pharmDx;
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available for their specific disease in the country where they are being treated); and
o Agreement to participate in biomarker analysis and have a tumor site that is safe to biopsy; ;• Part B1: any metastatic or advanced unresectable solid tumor or lymphoma (excluding thymic epithelial tumor, thymoma, or thymic carcinoma), measurable or nonmeasurable disease allowed, no further SOC therapy available;
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available for their specific disease in the country where they are being treated); ;• Part B2: any metastatic or advanced unresectable solid tumor or lymphoma (excluding thymic epithelial tumor, thymoma, or thymic carcinoma) with measurable disease allowed, no further SOC therapy available;
o Previous treatment with a PD-1/PD-L1 inhibitor;

o Discontinued treatment with PD-1/PD-L1 inhibitor for reasons other than toxicity;
o Naive to treatment with a CTLA-4 inhibitor; and
o Agreement to participate in biomarker analysis and have a tumor site that is safe to biopsy (only in cohorts receiving CX-072 + 3 mg/kg ipilimumab [but not 6 or
10 mg/kg ipilimumab]); ;• Part C: metastatic or advanced unresectable melanoma with BRAF V600E mutation-positive as detected by a diagnostic approved test (in the region where the pt is treated), measurable or nonmeasurable disease allowed;
o Naive to treatment with BRAF-inhibitor; and
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive ;• Part D: measurable disease is required;
* Must be willing to provide a blood sample at Screening for hTMB testing; and
* Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive (where there is no available life-prolonging immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy to the pt available for their specific disease in the country where they are being treated) of the following tumor types:
o UPS;
* Metastatic or advanced unresectable UPS;
* TPS >= 1% membranous staining or unknown PD-L1 status; and
* Subjects must have had SOC surgery and/or radiation for their UPS; subjects with metastatic disease should have received at least 1 prior systemic therapy according to local guidelines;
o Small bowel adenocarcinoma;
* Have metastatic or advanced unresectable small bowel adenocarcinoma of the duodenum, jejunum, ileum; and
* Subjects must have had at least 1 prior line of systemic chemotherapy for metastatic or advanced unresectable disease; adjuvant therapy does not count as first-line therapy unless cancer recurs < 6 months after last administration of that regimen;
o cSCC;
* Has primary cSCC that has metastasized to a distant site;
o MCC;
* Metastatic or advanced unresectable MCC;
* Prior surgical resection was performed if resectable or potentially of benefit; and
* Radiation therapy administered if of potential benefit with documented progression following completion of radiation therapy;
o Thymic carcinoma;
* Histologically confirmed diagnosis of thymic carcinoma (classified in accordance with 2004 World Health Organization criteria) with stage III or IV disease per Masaoka 1981; details provided in APPENDIX 2; and
* Received at least 1 prior chemotherapy regimen for thymic carcinoma;
o Anal SCC;
* Metastatic or advanced unresectable anal SCC; and
* Must have had prior radiation therapy plus chemotherapy treatment;
o TNBC;
* Must have histologically confirmed ER, progesterone receptor, and HER2 negative breast cancer; defined as ER < 1%, progesterone receptor < 1%, and HER2 negative according to ASCO/College of American Pathologists guidelines by local testing according to institutional standards. Subjects with weakly ER or progesterone receptor positive disease, defined as ER

and/or progesterone receptor < 5% by IHC, are eligible, if the treating physician considers the subject not eligible for endocrine therapy;
* Have locally advanced and locally recurrent skin or subcutaneous metastases not suitable for definitive (or curative) surgical resection or radiotherapy;
* Received at least 1 and no more than 3 systemic chemotherapy regimens for metastatic breast cancer and have documented disease progression on most recent therapy; and
* Willing to provide fresh tumor biopsy or archival tissue at Screening; and
o hTMB;
* Metastatic or advanced unresectable cancer with hTMB as determined using a Clinical Laboratory Improvement Amendments validated assay (at least 16/Mb) from the subject*s archival or fresh tumor tissue or blood after the last line of treatment;
* No evidence of microsatellite instability high; and
* Subject has failed or refused available SOC therapy specific for their tumor type. ;• Part E: measurable disease is required;
o Must be willing to provide a blood sample at screening for hTMB testing
o Immunotherapy naive, including PD-1/PD-L1 and CTLA-4 inhibitor therapy naive(where there is no available life-prolonging immunotherapy or PD-1/PD-L1 and CTLA-4 inhibitor therapy available to the pt) of the following tumor: UPS,small bowel adenocarcinoma,cSCC,MCC,TET,Anal SCC,TNBC,TNBC with skin lesions;Inclusion criteria for all subjects in all Parts:
1. Agreement to provide mandatory archival/baseline biopsy. A tumor biopsy is required at baseline if there is no other record of histological diagnosis of tumor; ;2. For pts in Part A2 or Part B2 (for Part B2, only those subjects receiving 3 mg/kg of ipilimumab), and those who agree to participate in the biomarker analysis and who have a tumor site that is safe to biopsy, subjects must have a biopsy within 90 days of study entry and be willing to undergo at least 1 on-treatment tumor biopsy; ;3. Patients with treated brain metastases are eligible if the brain metastases are stable and the patient does not require radiation therapy or steroids. Active screening for brain metastases (e.g., brain computed tomography [CT] or magnetic resonance imaging [MRI]) is not required; ;4. At least 18 years of age;;5. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1;;6. Anticipated life expectancy of at least 3 months;;7. Screening laboratory values must meet the following criteria:
• White blood cells > 2000/µL or

Exclusion criteria

1. Prior therapy with a chimeric antigen receptor (CAR) T-cell containing regimen;;2. Baseline QTc is > 470 ms or taking any medication known to prolong the QT interval; ;3. Prior history of myocarditis irrespective of the cause;;4. Treatment with strong cytochrome P450 (CYP) 3A4 inhibitors or inducers, as well as use of CYP1A2 substrates with a narrow therapeutic window assigned to the vemurafenib treatment arm.
http://medicine.iupui.edu/clinpharm/ddis/main-table/; ;5. History of severe allergic or anaphylactic reactions to human mAb therapy or known hypersensitivity to any Probody therapeutic; ;6. Active or history of uveal, mucosal, or ocular melanoma is excluded in Parts B2 and C;;7. History of interstitial lung disease for patients with TET are excluded in Part B1

and B2.;8. Human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS)-related illness, acute or chronic hepatitis B or C; patients with HIV that have an undetectable viral load and a CD4 cell count > 400/mL and who remain on antiretroviral regimen will be eligible for enrollment into anal SCC cohorts in Parts D and E and hTMB cohorts cohorts in Part D; ;9. History of or current active autoimmune diseases, including but not limited to inflammatory bowel diseases, rheumatoid arthritis, autoimmune thyroiditis, autoimmune hepatitis, systemic sclerosis, systemic lupus erythematosus, autoimmune vasculitis, autoimmune neuropathies, type 1 insulin dependent diabetes mellitus or myasthenia gravis. ;10. History of syndrome or medical condition(s) that requires systemic steroids (> 10 mg daily prednisone equivalents) or immunosuppressive medications; ;11. History of allogeneic tissue/solid organ transplant, prior stem cell or bone marrow transplant; ;12. Chemotherapy, biochemotherapy, radiation or immunotherapy within 14 days prior to receiving study drug; radiation therapy within 3 months prior to receiving study medication (except for radiotherapy for the purposes of palliation confined to a single field that is not the target lesion). ;13. Patients in Part C cannot have a glomerular filtration rate < 60mL/min/1.73 m2;;14. Major surgery (requiring general anesthesia) within 3 months or minor surgery (excluding biopsies conducted with local/topical anesthesia) or gamma knife treatment within 14 days (with adequate healing) of administration of any study drug; 15. Unresolved acute toxicity of the NCI CTCAE v4.03 Grade > 1 (or baseline, whichever is greater) from prior anti-cancer therapy. Alopecia and other nonacute toxicities are acceptable; ;16. History of malignancy that is active within the previous 2 years except for localized cancers that are not related to the current cancer being treated and considered to have been cured and, in the opinion of the Investigator, present a low risk for recurrence. These exceptions include, but are not limited to, basal or squamous cell skin cancer, superficial bladder cancer, or carcinoma in situ of the prostate, cervix or breast; ;17. Received a live vaccine within 30 days prior to first dose of study drug;;18. Known pre-existing condition of age-related macular degeneration;;19. Intercurrent illness, including, but not limited to, symptomatic congestive heart failure (i.e., New York Heart Association Class III or IV), unstable angina pectoris, clinically significant and uncontrolled cardiac arrhythmia, nonhealing wound or ulcer, or psychiatric illness/social situations that would limit compliance with study requirements; ;20. Pleural effusion, pericardial effusion, or recurrent ascites drainage.;21. Ongoing or active infection (including fever within 48 hours of Screening);;22. Participating in an ongoing clinical study involving treatment with medications, radiation, or surgery; or;23. Women who are pregnant or breastfeeding.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-10-2017
Enrollment:	64
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	89Zr-CX-072
Generic name:	-
Product type:	Medicine
Brand name:	CX-072
Generic name:	-
Product type:	Medicine
Brand name:	Yervoy
Generic name:	ipilimumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Zelboraf
Generic name:	vemurafenib
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-01-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-05-2017
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-08-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-03-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-05-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-07-2018
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-07-2019
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-07-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-03-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-07-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-09-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-11-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-12-2020
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2016-002490-36-NL
CCMO	NL59299.042.17

Study results

Date completed:	04-11-2020
Results posted:	14-02-2023
Actual enrolment:	22

First publication
14-11-2022