A Phase 2 Basket Study of Tucatinib in Combination with Trastuzumab in Subjects with Previously Treated, Locally Advanced Unresectable or Metastatic Solid Tumors Driven by HER2 Alterations

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Primary ObjectiveTo evaluate the antitumor activity of tucatinib given in combination with trastuzumab in subjects with previously treated, locally-advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2) overexpressing/...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51882

Source
ToetsingOnline

Brief title
Basket study of tucatinib and trastuzumab in solid tumors.

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Metastasis, Solid Tumor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Pharmaceutical industry

Intervention

Keyword: HER2-alternations, selected solid tumors, Trastuzumab, Tucatinib

Outcome measures

Primary outcome

Efficacy Assessments

Disease response will be assessed by the investigator according to RECIST v1.1. Treatment decisions will be made based upon local assessment of radiologic scans. Radiographic disease assessments will evaluate all known sites of disease, preferably using high quality spiral contrast computed tomography (CT) (with oral and/or IV contrast), and covering, at a minimum, the chest, abdomen, and pelvis. Positron emission tomography-CT scans (if high quality CT scan is included) and/or MRI scans may also be used as appropriate, as well as additional imaging of any other known sites of disease. In subjects with breast or lung cancer, a contrast MRI scan of the brain should be performed at screening. Subjects with known or suspected brain lesions should undergo brain MRIs during treatment and follow-up according to the same assessment schedule as for other disease assessments. If contrast is contraindicated (ie, in subjects with contrast allergy or impaired renal clearance), a non-contrast CT scan of the chest may be performed instead, with MRI scans of the abdomen and pelvis. For each subject, the same imaging modality as used at screening/baseline should be used throughout the study, unless otherwise

clinically indicated. Images will be collected by an independent central review (ICR) facility for possible future analysis. Disease assessments will be done at screening/baseline, and every 6 weeks for first 24 weeks then every 12 weeks, irrespective of dose interruptions.

Responses (CR or PR) will be confirmed with repeat scans at least 4 weeks after first documentation of response. The schedule for response assessments should not be adjusted after the confirmatory scan (eg, CR at Week 6, confirmatory scans at Week 10-12, next assessment due at Week 12). Tumor imaging should also be performed whenever disease progression is suspected.

Subjects will be considered evaluable for response if they (1) had a baseline disease assessment, (2) received study treatment, and (3) had a post baseline disease assessment or discontinued treatment due to documented disease progression or clinical progression.

Subjects that discontinue study treatment for reasons other than documented progressive disease or death will continue to have disease assessments every 6 weeks (±1 week) until 24 weeks after treatment initiation, then every 12 weeks (±1 week), until the occurrence of documented disease progression per RECIST v1.1, death, withdrawal of consent, lost to follow-up, or study closure.

Follow-up for survival and subsequent anti-cancer therapy will occur approximately every 12 weeks and continue until death, withdrawal of consent, lost to follow-up, or study closure.

Safety Assessments

Safety assessments will include the surveillance and recording of AEs, including serious adverse events (SAEs) and AESI, physical examination findings, vital signs, 12-lead electrocardiograms, concomitant medications, pregnancy testing, and laboratory tests. Assessment of cardiac ejection fraction will be performed using MUGA scan or echocardiogram. An ongoing, real-time review of subject safety and SAEs will be conducted by the sponsor*s Drug Safety Department. The SMC will be responsible for monitoring the safety of subjects in the study at regular intervals. AE and laboratory abnormality severity will be graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.

Secondary outcome

Pharmacokinetic Assessments

Blood samples for PK assessment of trough tucatinib drug levels will be collected in all subjects on Day 1 of Cycles 2 to 6, prior to administration of tucatinib. On Day 1 of Cycle 3, PK assessments of peak levels of tucatinib will be performed 1 to 4 hours after administration of tucatinib. Plasma concentrations of tucatinib will be determined using validated liquid chromatography (LC)-mass spectrometry (MS)/MS methods. PK parameters will be summarized using descriptive statistics.

HER2 Testing for Eligibility and Biomarker Assessments

Study eligibility requirements for HER2 overexpressing/amplified disease and

HER2-mutated disease are to be met by assays performed pre-study (assessments undertaken prior to any study-related actives) or in pre-screening, as follows:

1. Previously established HER2 alterations: HER2 eligibility can be demonstrated via HER2 overexpression or amplification in an IHC/ISH assay of tumor tissue or HER2 amplification or activating mutations in an NGS assay of ctDNA or tumor tissue, processed locally in a CLIA- or ISO-accredited laboratory before enrollment in the study.

2. Pre-screening for HER2 alterations: if HER2 alterations have not been detected in pre-study assessments, HER2 eligibility may alternatively be established during pre-screening, up to 3 months prior to the Screening visit, via an NGS assay of ctDNA evaluating the presence of HER2 amplification or mutations.

3. Additional samples for exploratory analyses: For exploratory analysis, all subjects will provide a blood sample for NGS assay of ctDNA and archival tumor tissue or a fresh tumor biopsy, if available. These will be provided either in pre-screening or, if pre-screening did not occur, at the Screening visit for tumor tissue and predose on Cycle 1 Day 1 for the blood sample. However, the blood sample does not need to be drawn if a pre-study NGS assay of ctDNA has previously been performed by the sponsor since the end of prior therapy. The results of this additional testing will not be used to determine eligibility.

Archival tumor tissue samples should be the most recent tissue sample available. If an archival sample is not available, a fresh biopsy will be undertaken at pre-screening or the Screening visit, if the subject has an available tumor lesion and consents to the biopsy. Subjects with no archival

tissue and whose tumors are considered not accessible or appropriate for biopsy are eligible for enrollment, following approval by the medical monitor.

Additional biomarker assessments may include an exploratory assessment of HER2 mutations or other mutations as potential biomarkers of response. Additional exploratory analyses including but not limited to IHC and NGS analysis may be performed to interrogate biomarkers that are associated with tumor growth, survival, and resistance to targeted therapeutics. This assessment may enable the correlation of additional biomarkers with treatment outcome and may ultimately guide or refine patient selection strategies to better match tucatinib regimens with tumor phenotype/genotype in the future.

Patient-Reported Outcomes Assessments

The EQ-5D-5L questionnaire will be administered to assess subject HRQoL. Administration will occur at Cycle 1 Day 1 prior to the start of study drug treatment and then on Day 1 of every second cycle, starting from Cycle 2. Additionally, a post-treatment assessment will be undertaken at the EOT visit.

Study description

Background summary

Somatic HER2 mutations occur in 7-8% of HR+ mBC (Bose 2013). Preclinical data suggests that resistance to anti-HER2-targeted therapies via upregulation of ER pathways can be suppressed by the addition of endocrine therapy (Giuliano 2013). For patients with tumors simultaneously expressing HR and HER2, guidelines support the combination of anti-HER2-targeted agents and endocrine therapy based on superior efficacy demonstrated in clinical trials (Rimawi 2018). It is hypothesized that if ER signaling is left uninhibited, it can become an alternative driver of cell growth and survival in ER+/HER2+ tumors in

the presence of HER2 inhibition (Giuliano 2015).
Fulvestrant is an injectable pure steroidal ER antagonist and has a high ER-binding affinity to produce complete receptor blockade. Fulvestrant*s lack of estrogen agonist activity is associated with reduced risk of endometrial abnormalities seen with tamoxifen (Bissett 1994; Early Breast Cancer Trialists' Collaborative Group (EBCTCG) 2005). Furthermore, fulvestrant uniquely impairs dimerization and the bound receptor is rapidly degraded (Steger 2005), blocking the nuclear ER as well as cytoplasmic and membrane-bound ER, which may limit the potential for cross-talk between EGFR/HER2-mediated pathways and delay the time to development of resistance to endocrine therapy (Wright 1992; Pietras 1995; Rusz 2018). Fulvestrant has clinical activity in patients previously treated with antiestrogen therapies, including aromatase inhibitors (Ingle 2006; Perey 2007) and in patients with ER+/HER2+ breast cancer (Steger 2005; Robertson 2010).
The results from the SUMMIT trial demonstrated that dual HER2-targeted therapy (neratinib and trastuzumab) with fulvestrant improved clinical benefit in patients with HR+ HER2-mutated mBC compared to neratinib combined with fulvestrant or neratinib monotherapy. The cohort who received neratinib + fulvestrant + trastuzumab demonstrated an ORR of 53% and median PFS of 9.8 months (Wildiers 2020) versus ORR of 30% in cohorts who received neratinib combined with fulvestrant (Smyth 2019) or neratinib monotherapy (Hyman 2018).

Study objective

Primary Objective
To evaluate the antitumor activity of tucatinib given in combination with trastuzumab in subjects with previously treated, locally-advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2) overexpressing/amplified or mutated solid tumors

Secondary Objective
To evaluate the safety and tolerability of tucatinib given in combination with trastuzumab with or without fulvestrant

Exploratory Objectives
• To evaluate the pharmacokinetics (PK) of tucatinib
• To explore any correlations between tissue and blood-based biomarkers and clinical outcomes
• To evaluate patient-reported outcomes (PROs)

Study design

This multi-cohort, open label, multicenter, international Phase 2 clinical study is designed to assess the activity, safety, and tolerability of tucatinib

in combination with trastuzumab for the treatment of selected solid tumors with HER2 alterations. Subjects will be enrolled into separate cohorts based on tumor histology and HER2 alteration status (see Table 1).
There are 5 tumor specific cohorts with HER2 overexpression/amplification (cervical cancer [Cohort 1], uterine cancer [Cohort 2], biliary tract cancer [Cohort 3], urothelial cancer [Cohort 4], and non-squamous non-small cell lung cancer [NSCLC] [Cohort 5]), 2 tumor specific cohorts with HER2 mutations (non squamous NSCLC and [Cohort 7] breast cancer [Cohort 8]), and 2 cohorts which will enroll all other HER2 amplified/overexpressed solid tumor types (except breast, gastric or gastroesophageal junction adenocarcinoma [GEC], and colorectal cancer [CRC]) or HER2 mutated solid tumor types (Cohorts 6 and 9 respectively).
If a sufficient number of subjects with a particular tumor type are enrolled in Cohorts 6 or 9, the sponsor may evaluate that tumor type in a separate cohort, drawn from optional Cohorts 10 to 15. If any optional cohort is opened, all subjects enrolled in Cohorts 6 or 9 with the applicable tumor type will be reassigned to the new tumor-specific cohort; these subjects will be replaced in Cohorts 6 and 9.
In Stage 1, up to approximately 12 response-evaluable subjects may be enrolled in each of Cohorts 1 to 5, and 7. If sufficient activity is observed in Stage 1 for a particular cohort (see Statistical Methods), up to a total of 30 response-evaluable subjects will be enrolled in the cohort (Stage 2 expansion) to further characterize the activity and safety of the study regimen in the given disease and HER2 alteration type. Cohorts 6, 8, and 9 will enroll up to 30 response-evaluable subjects without undergoing the Stage 1 assessment in 12 subjects. Subjects who are not response evaluable will be replaced.
Study treatment is composed of tucatinib 300 mg BID PO combined with trastuzumab 8 mg/kg intravenously (IV) on Cycle 1 Day 1 and then 6 mg/kg every 21 days starting on Cycle 2 Day 1. Subjects with hormone receptor (HR) positive (HR+), HER2-mutated breast cancer will also receive, in combination with tucatinib and trastuzumab, fulvestrant 500 mg intramuscular (IM) once every 4 weeks starting from Cycle 1 Day 1, as well as on Cycle 1 Day 15. A Safety Monitoring Committee (SMC) will be responsible for monitoring the safety of subjects in the study at regular intervals. Subjects will continue study treatment until the occurrence of radiographic or clinical progression, unacceptable toxicity, withdrawal of consent, death, or study closure.
Following treatment discontinuation, disease progression, further anti-cancer therapy, and survival status will be monitored until withdrawal of consent, death, or study closure. The study will be closed approximately 3 years after the last subject is enrolled or when no subjects remain in long-term follow-up, whichever occurs first. Additionally, the sponsor may terminate the study at any time.

Intervention

Tucatinib 300 mg will be administered PO BID continuously starting from Cycle 1 Day 1 onwards.

Trastuzumab 8 mg/kg will be administered IV on Cycle 1 Day 1 and then will be administered at 6 mg/kg every 21 days starting on Cycle 2 Day 1. However, if trastuzumab IV was administered within the 4 weeks prior to treatment initiation, trastuzumab 6 mg/kg IV should be administered on Cycle 1 Day 1. Fulvestrant 500 mg will be administered IM once every 4 weeks starting from Cycle 1 Day 1, as well as on Cycle 1 Day 15

Duration of Treatment
Study treatment will continue until unacceptable toxicity, occurrence of radiographic progression or clinical progression, withdrawal of consent, death, or study closure. If a study drug (tucatinib, trastuzumab, or fulvestrant) is discontinued, study treatment can continue with remaining study drug(s).

Study burden and risks

N/A

Contacts

Public
Selecteer

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NL
Scientific
Selecteer

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Schiphol 1118 CL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Histologically or cytologically confirmed diagnosis of locally-advanced unresectable or metastatic solid tumor, including primary brain tumors
2. Subjects with disease types other than breast cancer, biliary tract cancer, non-squamous NSCLC, and cervical cancer: Disease progression on or after the most recent systemic therapy for locally-advanced unresectable or metastatic disease
3. Subjects with any breast cancer subtype:
a. Must have HER2-mutated disease which does not display HER2 overexpression/amplification
b. Must have progressed on or after >=1 prior line of treatment (chemotherapy, endocrine therapy, or targeted therapy) for locally-advanced unresectable or metastatic breast cancer
c. Subjects with metastatic HR+ HER2-mutated disease must have received a prior CDK4/6 inhibitor in the metastatic setting
4. Subjects with biliary tract cancer: must have progressed on or after >=1 prior line of treatment (chemotherapy, endocrine therapy, or targeted therapy)
5. Subjects with non-squamous NSCLC: has relapsed from or is refractory to standard treatment or for which no standard treatment is available
6. Subjects with cervical cancer:
a. Subjects with metastatic cervical cancer must have progressed on or after >=1 prior line of systemic therapy (platinum-based chemotherapy with or without bevacizumab) in the metastatic setting
b. Subjects with locally advanced unresectable cervical cancer must have progressed on or after >=1 prior lines of systemic therapy
7. Disease demonstrating HER2 alterations (overexpression/amplification or HER2 activating mutations), as determined by local or central testing processed in a Clinical Laboratory Improvement Amendments (CLIA)- or International Organization for Standardization (ISO) accredited laboratory, according to one of the following:
a. HER2 overexpression/amplification from fresh or archival tumor tissue or blood utilizing one of the following tests, in subjects with tumor types other than breast cancer, GEC, or CRC:
i. HER2 overexpression (3+ immunohistochemistry IHC) (breast or gastric algorithms)
ii. HER2 amplification by in situ hybridization assay (fluorescence in situ hybridization [FISH] or chromogenic in situ hybridization signal ratio >=2.0 or gene copy number >6)
iii. HER2 amplification in tissue by next generation sequencing (NGS) assay
iv. HER2 amplification in circulating tumor DNA (ctDNA) by blood-based NGS assay
b. Known activating HER2 mutations detected in fresh or archival tumor tissue

or blood by NGS assay, including:
o Extracellular domain: G309A/E; S310F/Y; C311R/S; C334S
o Kinase domain: T733I; L755P/S; I767M; L768S; D769N/Y/H; Y772; A775; G776; V777L/M; G778; T798; L841V, V842I; N857S, T862A, L869R, H878Y, R896C
o Transmembrane/juxtamembrane domain: S653C, I655V; V659E; G660D; R678Q; V697.
o Subjects with HER2 activating mutations not listed above may be eligible, if supported by scientific literature and approved by the medical monitor
8. Have measurable disease per RECIST v1.1 criteria according to investigator assessment
9. Be at least 18 years of age at time of consent, or considered an adult by local regulations
10. Have Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
11. Have a life expectancy of at least 3 months, in the opinion of the investigator
12. Have adequate hepatic function as defined by the following:
a. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) <=3 × upper limit of normal (ULN) (<=5 × ULN if liver metastases are present)
b. Total bilirubin <=1.5 × ULN. Exception: subjects with known history of Gilbert's Syndrome and normal direct bilirubin, AST, and ALT are eligible
13. Have adequate baseline hematologic parameters as defined by:
a. Absolute neutrophil count (ANC) >=1.0 ×109/L
b. Platelet count >=100 × 109/L; subjects with stable platelet count from 75 to 100 × 109/L may be included with approval from Medical Monitor
c. Hemoglobin >=9.0 g/dL; subjects with hemoglobin >=8 and <9 g/dL may be included with approval from the Medical Monitor
d. In subjects transfused before study entry, transfusion must be >=14 days prior to start of therapy to establish adequate hematologic parameters independent from transfusion support
14. Estimated glomerular filtration rate (GFR) >=30 mL/min/1.73 m^2 using the Modification of Diet in Renal Disease (MDRD) study equation
15. International normalized ratio (INR) and activated partial thromboplastin time (aPTT) <=1.5 × ULN unless receiving a medication known to alter INR and aPTT
16. Left ventricular ejection fraction (LVEF) >=50% as assessed by echocardiogram or multiple-gated acquisition scan (MUGA) documented within <=28 days prior to first dose of study treatment
17. For subjects of childbearing potential, the following stipulations apply:
a. Must have a negative serum or urine pregnancy test (minimum sensitivity of 25 mIU/mL or equivalent units of beta human chorionic gonadotropin [β-hCG]) result within 7 days prior to the first dose of study treatment. A subject with a false positive result and documented verification that the subject is not pregnant is eligible for participation.
b. Must agree not to try to become pregnant during the study and for at least 7 months after the final dose of any study drug, and, if applicable, for at least 2 years after the final dose of fulvestrant.
c. Must agree not to breastfeed or donate ova, starting at time of informed consent and continuing through at least 7 months after the final dose of any study drug, and, if applicable, at least 2 years after the final dose of

fulvestrant.
d. If sexually active in a way that could lead to pregnancy, must consistently use 2 highly effective methods of birth control, as defined in Appendix B, starting at the time of informed consent and continuing throughout the study and for at least 7 months after the final dose of any study drug, and, if applicable, for at least 2 years after the final dose of fulvestrant.
18. For subjects who can father children, the following stipulations apply:
a. Must agree not to donate sperm starting at time of informed consent and continuing throughout the study period and for at least 7 months after the final dose of any study drug, and, if applicable, for at least 2 years after the final dose of fulvestrant.
b. If sexually active with a person of childbearing potential in a way that could lead to pregnancy, must consistently use 2 highly effective methods of birth control, starting at time of informed consent and continuing throughout the study and for at least 7 months after the final dose of any study drug, and, if applicable, for at least 2 years after the final dose of fulvestrant.
c. If sexually active with a person who is pregnant or breastfeeding, must consistently use one of 2 methods of birth control, as defined in Appendix B, starting at time of informed consent and continuing throughout the study and for at least 7 months after the final dose of any study drug, and, if applicable, for at least 2 years after the final dose of fulvestrant.
19. Subject must provide signed informed consent that has been approved by an institutional review board/independent ethics committee (IRB/IEC) prior to initiation of any study-related tests or procedures that are not part of standard-of-care for the subject*s disease
20. Subject must be willing and able to comply with study procedures

Exclusion criteria

1. Subjects with breast cancer, GEC, or CRC whose disease shows HER2 amplification/overexpression.
2. Previous treatment with HER2-directed therapy; subjects with uterine serous carcinoma may have received prior trastuzumab
3. Known hypersensitivity to any component of the drug formulation of tucatinib or trastuzumab (drug substance, excipients, murine proteins), or any component of the drug formulation of fulvestrant in subjects with HR+ HER2-mutated breast cancer
4. History of exposure to a >360 mg/m² doxorubicin-equivalent or >720 mg/m² epirubicin-equivalent cumulative dose of anthracyclines
5. Treatment with any systemic anti-cancer therapy, radiation therapy, or experimental agent within <=3 weeks of first dose of study treatment or are currently participating in another interventional clinical trial.
6. Have any toxicity related to prior cancer therapies that has not resolved to <= Grade 1, with the following exceptions:
a. Alopecia

b. Congestive heart failure (CHF), which must have been <= Grade 1 in severity at the time of occurrence, and must have resolved completely
c. Anemia, which must have resolved to <= Grade 2
7. Have clinically significant cardiopulmonary disease such as:
a. Ventricular arrhythmia requiring therapy
b. Symptomatic hypertension or uncontrolled hypertension as determined by investigator
c. Any history of symptomatic CHF
d. Severe dyspnea at rest (National Cancer Institute Common Terminology Criteria for Adverse Events [NCI CTCAE] Grade 3 or above) due to complications of advanced malignancy
e. Hypoxia requiring supplementary oxygen therapy except when oxygen therapy is needed only for obstructive sleep apnea
8. Have known myocardial infarction or unstable angina within 6 months prior to first dose of study treatment
9. Known to be positive for hepatitis B by surface antigen expression. Known to be positive for hepatitis C infection (positive by polymerase chain reaction). Subjects who have been treated for hepatitis C infection are permitted if they have documented sustained virologic response of 12 weeks
10. Presence of known chronic liver disease
11. Subjects known to be positive for human immunodeficiency virus (HIV) are excluded if they meet any of the following criteria:
• CD4+ T-cell count of <350 cells/µL
• Detectable HIV viral load
• History of an opportunistic infection within the past 12 months
• On stable antiretroviral therapy for <4 weeks
12. Are pregnant, breastfeeding, or planning a pregnancy from time of informed consent until 7 months after the final dose of any study drug, and, if applicable, for at least 2 years after the final dose of fulvestrant
13. Have inability to swallow pills
14. Have used a strong cytochrome P450 (CYP) 2C8 inhibitor within 5 half-lives of the inhibitor, or have used a strong CYP3A4 or CYP2C8 inducer within 5 days prior to start of treatment
15. Have any other medical, social, or psychosocial factors that, in the opinion of the investigator, could impact safety or compliance with study procedures
16. History of another malignancy within 2 years prior to screening, with the exception of those with a negligible risk of metastasis or death (eg, 5-year OS of >=90%), such as adequately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer
17. Subjects with known central nervous system (CNS) lesions must not have any of the following:
a. Any untreated brain lesions >2.0 cm in size, unless approved by the medical monitor
b. Ongoing use of systemic corticosteroids for control of symptoms of brain lesions at a total daily dose of >2 mg of dexamethasone (or equivalent).

However, subjects on a chronic stable dose of <=2 mg total daily of dexamethasone (or equivalent) may be eligible, following approval by the medical monitor
c. Any brain lesion thought to require immediate local therapy, including (but not limited to) a lesion in an anatomic site where increase in size or possible treatment-related edema may pose risk to subject (eg, brain stem lesions). Subjects who undergo local treatment for such lesions identified by screening brain magnetic resonance imaging (MRI) may still be eligible for the study
d. Known or suspected leptomeningeal disease as documented by the investigator
e. Have poorly controlled (>1/week) generalized or complex partial seizures, or manifest neurologic progression due to brain lesions notwithstanding CNS-directed therapy

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Faslodex
Generic name:	Fulvestrant
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Herceptin

Generic name:	Trastuzumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tukysa
Generic name:	Tucatinib

Ethics review

Approved WMO Date:	18-03-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-04-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	01-02-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-02-2023
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2020-004873-29-NL
ClinicalTrials.gov	NCT04579380
CCMO	NL76151.031.21