

Clinical Performance Study Plan for use of HercepTest* mAb pharmDx (Dako Omnis) and HER2 IQFISH pharmDx with Gastric or Gastroesophageal Junction Cancer Specimens

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The objective of this study is to evaluate the performance of HercepTest* mAb pharmDx (Dako Omnis) (GE001) and HER2 IQFISH pharmDx (K5731) in identifying subjects with HER2 positivity (IHC 3+ or IHC 2+/ISH +) for the clinical trial DESTINY-Gastric05...

Ethical review	Approved WMO
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON57550

Source

ToetsingOnline

Brief title

IVD PS D0118538 Using Patient Samples from DESTINY-Gastric05

Synonym

Gastroesophageal Junction Cancer, Stomach cancer

Health condition

Oncology - Gastric or Gastroesophageal Junction Cancer

Research involving

Human

Sponsors and support

Primary sponsor: Daiichi Sankyo, Inc

Source(s) of monetary or material Support: funded by the sponsor

Intervention

Keyword: Gastric cancer, Gastroesophageal Junction Cancer, IVD

Outcome measures

Primary outcome

The primary endpoint of the trial is progression free survival as assessed by Blinded Independent Central Review, defined as the time interval from the date of randomization to the date of radiographic disease progression or death due to any cause. The objective of the primary efficacy analysis is to compare the progression free survival between the two arms within each cohort.

Secondary outcome

The key secondary endpoint is overall survival, defined as the time interval from the date of randomization to the date of death due to any cause. The objective of the key secondary efficacy analysis is to compare the overall survival between the two arms within each cohort.

Calculate incidences of, for example, serious adverse events, treatment-emergent adverse events to assess safety and tolerability between arms within each cohort.

Study description

Background summary

HercepTest* mAb pharmDx (Dako Omnis) and HER2 IQFISH pharmDx will be used for HER2-positive patient selection in the DESTINY-Gastric05 clinical trial.

HercepTest* mAb pharmDx (Dako Omnis) is a semi-quantitative immunohistochemical assay based on a primary monoclonal rabbit antibody (clone DAK-HcT-2 (DG44)) and an assay-specific visualization reagent. The assay determines HER2 protein overexpression in formalin-fixed, paraffin-embedded (FFPE) human cancer tissues processed for histological evaluation. HercepTest* mAb pharmDx (Dako Omnis) is for automated staining using Dako Omnis.

HER2 IQFISH pharmDx is a direct fluorescence in situ hybridization (FISH) assay designed to quantitatively determine HER2 gene amplification in FFPE tissue from patients with metastatic gastric or GEJ adenocarcinoma.

The current best practice of HER2 testing in gastric cancer is based on American Society of Clinical Oncology - College of American Pathologist (ASCO-CAP) publication 24. HER2 positivity of gastric or GEJ cancer is defined as centrally determined HER2 positive (IHC 3+ or IHC 2+/ISH +) as classified by ASCO-CAP.

Study objective

The objective of this study is to evaluate the performance of HercepTest* mAb pharmDx (Dako Omnis) (GE001) and HER2 IQFISH pharmDx (K5731) in identifying subjects with HER2 positivity (IHC 3+ or IHC 2+/ISH +) for the clinical trial DESTINY-Gastric05.

Study design

DESTINY-Gastric05 is a multicenter, randomized, open-label, Phase 3 clinical trial, is designed to assess the efficacy and safety of the triplet combination of trastuzumab deruxtecan (ENHERTU®, T-DXd, DS-8201a) plus a fluoropyrimidine plus pembrolizumab versus Standard of Care (SoC) chemotherapy plus trastuzumab plus pembrolizumab as first-line therapy in participants with unresectable, locally advanced or metastatic HER2-positive tumor (determined by HercepTest* mAb pharmDx (Dako Omnis) and HER2 IQFISH pharmDx) PD-L1 CPS ≥ 1 (determined by PD-L1 IHC 22C3 pharmDx, demonstrated in a separate CPSP D0118539) gastric or GEJ cancer in the Main Cohort. HER2 positive, PD-L1 CPS < 1 population will be enrolled to Exploratory Cohort.

Intervention

Biopsies will be obtained in the context of the pharmaceutical study (only in the event that a suitable archived sample is not available)

Study burden and risks

Collection of tissue biopsy is considered part of standard clinical to determine the most appropriate therapeutic option for Gastric or

Gastroesophageal Junction cancer patients.

The possible complications include: bleeding, bruising, swelling, infection, or scarring at the site of the biopsy. A brief, sharp pain from the needle used for anesthesia. The biopsy needle will produce a dull pain.

Very rarely, complications from biopsies can be life-threatening.

Potentially serious complications from bleeding or organ damage may occur that might require additional surgical intervention. There is a risk of regional spread of cancer cells when the needle is removed from the tumor.

There is a chance of false results. A false positive result may lead to study drugs that are not medically necessary and also may result in side effects. A false negative result may occur, leading to being excluded from this study, and not receiving the study drugs. There is a risk of delays in obtaining and/or providing results, and a risk that additional samples or re-biopsy may be required.

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

Sign and date the Tissue Prescreening ICF, prior to HER2 and PD-L1 CPS central testing.

- All participants must provide a tumor sample for tissue-based IHC staining to centrally determine HER2 expression and PD-L1 CPS status.
- Enrollment in this clinical study is based on centrally determined HER2 positive (IHC 3+ or IHC 2+/ISH+) gastric or GEJ cancer as classified by ASCO-CAP for gastric cancer on a tumor biopsy as detected by prospective central test on new (core, incisional, excisional biopsy) or existing tumor tissue taken at the time of diagnosis of locally advanced or metastatic disease.
- Centrally determined tumor PD-L1 CPS status using the PD-L1 IHC 22C3 PharmDx:
 - For the Main Cohort: PD-L1 CPS ≥ 1
 - For the Exploratory Cohort: PD-L1 CPS < 1

Exclusion criteria

- Prior exposure to other HER2-targeting therapies.
- Cytology specimens or decalcified tissues.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 23-03-2025

Enrollment: 15

Type: Anticipated

Medical products/devices used

Generic name: HercepTest[®] mAb pharmDx (Dako Omnis); HER2 IQFISH pharmDx

Registration: Yes - CE outside intended use

Ethics review

Approved WMO

Date: 21-05-2025

Application type: First submission

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL88600.000.24