Clinical Performance Study Plan for use of PD-L1 IHC 22C3 pharmDx pharmDx with Gastric or Gastroesophageal Junction Cancer Specimens

Published:
Last updated: 28-05-2025

The objective of this study is to evaluate the performance of PD-L1 IHC 22C3 pharmDx (SK006) in identifying subjects whose tumor with PD-L1 CPS >=1 to be enrolled to the Main Cohort and with PD-L1 CPS

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

Summary

ID

NL-OMON57545

Source
ToetsingOnline

Brief title
IVD PS D0118539 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.

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.

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

For additional endpoints, refer to CSP (Attachment 5).

Study description

Background summary

PD-L1 IHC 22C3 pharmDx will be used for cohort assigned in the DESTINY-Gastric05 clinical trial, based on PD-L1 expression level.
PD-L1 IHC 22C3 pharmDx contains optimized reagents and protocol required to complete an IHC staining procedure of FFPE specimens using Autostainer Link 48.

Study objective

The objective of this study is to evaluate the performance of PD-L1 IHC 22C3 pharmDx (SK006) in identifying subjects whose tumor with PD-L1 CPS >=1 to be enrolled to the Main Cohort and with PD-L1 CPS <1 to be enrolled to the Exploratory Cohort in 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, demonstrated in a separate CPSP D0118538 4) PD-L1 CPS >=1 (determined by PD-L1 IHC 22C3 pharmDx) 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:	PD-L1 IHC 22C3 pharmDx
Registration:	Yes - CE outside intended use

Ethics review

Not available

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	NL88617.000.24