Clinical Performance Study Plan (CPSP) For Use of the CLDN18.2 (SP455) Clinical Trial Assay to select CLDN18.2 positive patients for recruitment into the AstraZeneca Phase I/II study of AZD5863 in adult participants with advanced or metastatic solid tumours

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This clinical performance study will evaluate the effectiveness of the CLDN18.2 (SP455) Clinical Trial Assay in identifying CLDN18.2 status in Adult Participants with Advanced or Metastatic Solid Tumours treated with AZD5863.

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

Summary

ID

NL-OMON57058

Source
ToetsingOnline

Brief title
D9750C00001

Condition

- Metastases

Synonym
metastatic solid tumors, Selected metastatic solid tumors expressing CLDN18.2

Research involving
Human

Sponsors and support

Primary sponsor: Astra Zeneca
Source(s) of monetary or material Support: AstraZeneca

Intervention

Keyword: CLDN18.2, Clinical Trial Assay, Solid tumours, SP455

Outcome measures

Primary outcome

Performance study endpoint is to demonstrate that the CLDN18.2 (SP455) CTA is safe and effective to identify patients for AZD5863, as supported by the efficacy and safety endpoints from the D9750C00001 clinical trial as defined by the ORR.

Secondary outcome

Not applicable.

Study description

Background summary

This clinical performance study protocol (CPSP) relates to the use of the CLDN18.2 (SP455) Clinical Trial Assay (CTA) to identify and select CLDN18.2 positive (CLDN18.2 expression level >=25% in tumor cells) gastric/GEJ carcinoma, esophageal adenocarcinoma, and pancreatic cancer patients for recruitment into the AstraZeneca Phase I/II Open-label Dose Escalation and Dose Expansion Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of AZD5863, a T cell-engaging Bispecific Antibody that Targets Claudin 18.2 (CLDN18.2) and CD3 in Adult Participants with Advanced or Metastatic Solid Tumors (D9750C00001).

Study objective

This clinical performance study will evaluate the effectiveness of the CLDN18.2 (SP455) Clinical Trial Assay in identifying CLDN18.2 status in Adult Participants with Advanced or Metastatic Solid Tumours treated with AZD5863.

Study design

The CLDN18.2 (SP455) Clinical Trial Assay is an investigational device intended to identify CLDN18.2 expression in adult participants with advanced metastatic solid tumours, gastric/GEJ carcinoma, esophageal adenocarcinoma, and pancreatic cancer in formalin-fixed, paraffin-embedded (FFPE) tissue as part of the enrolment criteria for clinical drug trial D9750C00001.
Outcome data from clinical drug trial D9750C00001 will be used to evaluate the clinical performance of CLDN18.2 (SP455) Clinical Trial Assay as an IVD for AZD5863 as a monotherapy or in combination in patients with advanced or metastatic solid tumours,

The study consists of Module 1 (AZD5863 monotherapy intravenously) and Module 2 (AZD5863 monotherapy subcutaneously), and each module will contain dose escalation (part A) and dose-expansion (part B).
Participants will be based on prospective testing of CLDN18.2 expression using the device described in this clinical performance study protocol.

Intervention

If not present: collection of a tumor biopsy.

Study burden and risks

A new biopsy may have to be collected during screening if there is no or not enough tissue available.

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

- Histologically confirmed diagnosis of adenocarcinoma of the stomach, gastro-esophageal junction, esophagus, or pancreas
- Participants must have received at least one prior line of systemic therapy in the advanced/metastatic setting
- ECOG performance status of 0 or 1 at screening
- Predicted life expectancy of >= 12 weeks
- Must have at least one measurable lesion according to RECIST v1.1
- Participants must show CLDN18.2 expression in >=25% tumor cells as determined by central IHC. Archival tissue blocks up to 3 years old or archival cut slides up to 6 months old (from the time of signing pre-screening ICF) or fresh tissue are all acceptable for IHC

Exclusion criteria

- Unresolved toxicity from prior anticancer therapy of Common Terminology Criteria for Adverse Events (CTCAE) Grade >= 2 except for vitiligo, alopecia, etc. - Participant experienced Grade >=3 CRS or Grade >=2 ICANS based on ASTCT criteria following prior TCE or CAR-T cell therapy - Active or prior documented autoimmune or inflammatory disorders - CNS metastases or CNS pathology including: epilepsy, seizures, paresis, aphasia etc. Participants with brain metastases treated, asymptomatic, stable, and not requiring continuous corticosteroids at a dose of > 10 mg prednisone/day are allowed - Participants with clinically significant ascites that require drainage. - Oesophageal cancer with airway involvement. - Infectious disease including active HIV, active hep

B/C, uncontrolled active systemic fungal, bacterial or other infection

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2024
Enrollment:	8
Type:	Anticipated

Medical products/devices used

Generic name:	CLDN18.2 (SP455) Clinical Trial Assay
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	25-06-2024
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
Other	EU-CT number: 2023-504139-42
CCMO	NL86495.000.24