Clinical Performance Study Plan for use of B7-H4 (A57.1) Clinical Trial Assay for Patient Enrolment Into The Clinical study (D6900C00001), titled *A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic Solid Malignancies*.

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

Summary

ID

NL-OMON53228

Source
ToetsingOnline

Brief title
AZD8205 in participants with metastatic solid malignancies

Condition

- Metastases

Synonym
metastatic solid tumors, Selected metastatic solid tumors expressing B7-H4

Research involving
Human

Sponsors and support

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

Intervention

Keyword: B7-H4, Clinical Trial Assay

Outcome measures

Primary outcome

The primary objective of this clinical performance study is to evaluate the

effectiveness of the B7-H4 (A57.1) CTA in identifying B7-H4 positive (B7-H4

membrane staining at any intensity in >=25% tumor cells) ovarian, endometrial,

biliary tract and breast cancer

Secondary outcome

Not applicable

Study description

Background summary

This clinical performance study protocol (CPSP) relates to the use of the B7-H4 (A57.1) Clinical Trial Assay (CTA) to identify and select B7-H4 positive (B7-H4 expression level at any intensity on the tumor cell surface in >=25% tumor cells) ovarian, endometrial, biliary tract and breast cancer patients for

recruitment into the AstraZeneca Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic Solid Malignancies (D6900C00001).

Study objective

The primary objective of this clinical performance study is to evaluate the effectiveness of the B7-H4 (A57.1) CTA in identifying B7-H4 positive (B7-H4 membrane staining at any intensity in >=25% tumor cells) ovarian, endometrial, biliary tract and breast cancer patients for recruitment into the AstraZeneca Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic Solid Malignancies (D6900C00001) study.
The B7-H4 scoring data from the baseline clinical samples will be analyzed in relation to clinical outcomes to determine the predictive value of the B7-H4 biomarker for AZD8205. Statistical analysis will include, but will not be limited to: descriptive statistical analysis, logistic regression analysis, receiver operating characteristic (ROC) curve, and Youden index.

Study design

The assay was developed to test B7-H4 on tumor material from patients participating in the study: AstraZeneca Phase I/IIa Multi-center, Open-label Master to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of AZD8205 in participants with Advanced or metastatic solid malignancies (D6900C00001). If patient has >50% expression of B7-H4 he/she can participate in the study.
The study consists of 4 cohorts: biliary tract cancer, ovarian cancer, breast cancer and endometrial cancer

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

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Eastern Cooperative Oncology Group PS 0-1.
Participants with relapsed/metastatic solid tumors (biliary tract cancer, ovarium cancer, breast cancer or endometrial cancer) must have received prior adequate SoC therapy for their tumor type and stage of disease
Participants must have measurable disease per RECIST v1.1
Life expectancy >= 12 weeks
Adequate organ function
The respective cohorts for patient inclusion are:
- Cohort 1: Biliary tract cancer
- Cohort 2: Ovarian cancer
- Cohort 3: Breast cancer
- Cohort 4: Endometrial cancer

Exclusion criteria

Participants with spinal cord compression or a history of leptomeningeal carcinomatosis
Participants with brain metastases unless treated, asymptomatic, stable
Unresolved toxicities of Grade >= 2 (NCI CTCAE v5.0) from prior therapy
Active infection, including tuberculosis and infections with HBV, HCV or HIV
Has a history of (non-infectious) ILD/pneumonitis that required steroids, has current
ILD/pneumonitis
Clinically severe pulmonary compromise resulting from intercurrent pulmonary illnesses
History of another primary malignancy
Participants with History of arrhythmia, Uncontrolled hypertension, Acute coronary syndrome/acute myocardial infarction, unstable angina pectoris and other heart diseases
Uncontrolled intercurrent illness

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2024
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	B7-H4 (A57.1) Clinical Trial Assay
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	11-09-2023
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: 2022-502759-70-00
CCMO	NL84167.056.23