Clinical Performance Study Protocol for Use of VENTANA PD-L1 (SP263) CDx Assay in AstraZeneca Study D798AC00001(eVOLVE-Lung02): A Phase III, Two-Arm, Parallel, Randomized, Multi-Center, Open-Label, Global Study to Determine the Efficacy of Volrustomig (MEDI5752) Plus Chemotherapy Versus Pembrolizumab Plus Chemotherapy for First-Line Treatment of Patients with Metastatic Non-Small Cell Lung Cancer (mNSCLC) (eVOLVE-Lung02)

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

Summary

ID

NL-OMON56319

Source
ToetsingOnline

Brief title
eVOLVE-Lung02

Condition

- Metastases

Synonym
Metastatic Non-Small Cell Lung Cancer with PD-L1<50%, Non-Small Cell Lung Cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: PD-L1 assay, Volrustomig

Outcome measures

Primary outcome

- Progression free survival (PFS) in the PD-L1 TC <1% population. PFS is

defined as the time from randomization until radiological progression per

RECIST 1.1 as assessed by blinded independent central review (BICR), or death

due to any cause (in the absence of progression)

- Overall survival (OS) in the PD-L1 TC <1% population. OS is defined as the

time from randomization until the date of death due to any cause

Secondary outcome

- PFS in all randomized participants (PD-L1 TC <50%)

- OS in all randomized participants (PD-L1 TC <50%)

Study description

Background summary

The current state of the art in medicine for the target population under investigation in AstraZeneca Study eVOLVE-Lung02 is immunotherapy (i.e, anti-PD-[L]1 therapy), administered alone or in combination with standard of care chemotherapy. There is a subset of patients (namely, the PD-L1 TC <50% population) where current approved immunotherapies alone or in combination have limited therapeutic effect, underlying the need for improved therapeutic options for this patient population. Preclinical and clinical data suggest there is synergy between PD-(L)1 inhibition and CTLA-4 inhibition and that the clinical benefit from this combination is seen amongst patients with PD-L1 TC <50%.

As part of a co-development paradigm including both an investigational therapy and an investigational IVD device, RTD, as the IVD device manufacturer, will be responsible for certain aspects of the investigational IVD use within AstraZeneca Study eVOLVE-Lung02. As such, this protocol supports AstraZeneca Study eVOLVE-Lung02 by describing the procedures for how the patient tumor samples, collected as part of AstraZeneca Study eVOLVE-Lung02, should be tested prospectively with VENTANA PD-L1 (SP263) CDx Assay at the Dx testing sites.

Study objective

The primary objective of the clinical performance study is to demonstrate the clinical performance of VENTANA PD-L1 (SP263) CDx Assay in terms of its ability to identify NSCLC patients who may benefit from treatment with volrustomig plus chemotherapy. PD-L1 expression level of NSCLC tumor specimens will be determined for patient selection (TC <50%) and stratification (PD-L1 TC <1% versus PD-L1 TC 1% to 49%) in support of AstraZeneca Study eVOLVE-Lung02.

Study design

VENTANA PD-L1 (SP263) CDx Assay will be used to assess the PD-L1 expression level of NSCLC tumor specimens collected from patients who are being screened to determine eligibility to participate in AstraZeneca Study eVOLVE-Lung02. It is anticipated that tumor specimens from approximately 1800 subjects undergoing screening to participate in AstraZeneca Study eVOLVE-Lung02 will be tested with VENTANA PD-L1 (SP263) CDx Assay at Dx testing sites.

Stained slides from each case will be interpreted by qualified pathologists who

will assign a PD-L1 expression level at the 1% TC (<1% versus >=1%) and at the 50% TC (<50% versus >=50%) thresholds. A PD-L1 expression level at <50% TC will be one of the factors used to determine eligibility for enrolling patients into AstraZeneca Study eVOLVE-Lung02. Additionally, PD-L1 expression level at the 1% TC threshold (<1% versus 1% to 49%) will be one of the stratification factors used for randomization of patients into the treatment arms of AstraZeneca Study eVOLVE-Lung02. For each case, a PD-L1 expression level will also be assigned at the 25% TC threshold and both raw TC scores and raw immune cell (IC) scores will be recorded for
exploratory purposes.

Intervention

If not present: a tumor biopsy is collected at screening

Study burden and risks

A new biopsy may have to be taken during screening if no or not enough tissue is 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

1. It must be an FFPE tumor specimen submitted for AstraZeneca Study eVOLVE-Lung02 under appropriate patient informed consent and processed in accordance with standard practice;
2. It must contain sufficient tissue for interpretation at the discretion of the reviewing pathologist; and
3. If an FFPE tissue block is unavailable, unstained FFPE slides can be submitted

Exclusion criteria

A specimen will be excluded from staining with the investigational essay if any of the following conditions apply:

1. It was known to be fixed in alcohol-formalin-acetic acid (AFA), 95% alcohol or any other alcohol-based fixative, or;
2. It consists of tissue that has been decalcified;
3. It is a fine needle aspirate or cytology specimen; or
4. Cut slides were prepared over 12 months prior to staining

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2024
Enrollment:	32
Type:	Anticipated

Medical products/devices used

Generic name:	VENTANA PD-L1 (SP263) Assay
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	30-11-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-05-2024
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
CCMO	NL84913.000.23