Clinical Performance Study Protocol for Use of VENTANA PD-L1 (SP263) CDx Assay in [redacted]

Published: 22-05-2024
Last updated: 07-06-2025

The objective of this study is to establish the clinical performance of VENTANA PD-L1 (SP263) CDx Assay as a companion diagnostic (CDx) for the identification of patients with NSCLC who may benefit from treatment with [redacted]. ...

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON56986

Source
ToetsingOnline

Brief title
GSK GALAXIES LUNG-301 PD-L1

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
locally advanced Lung Cancer unresectable or metastatic NSCLC

Research involving
Human

Sponsors and support

Primary sponsor: Ventana Medical Systems, Inc. (Roche Tissue Diagnostics)
Source(s) of monetary or material Support: Ventana Medical System, Inc. (Roche Tissue Diagnostics)

Intervention

- In-vitro diagnostic

Keyword: in vitro diagnostic assay, Non-Small-Cell-Lung Cancer (NSCLC)

Explanation

N.a.

Outcome measures

Primary outcome

The primary endpoints of the clinical performance study are the primary efficacy endpoints described in [redacted] Study protocol, as listed below:
• Progression-free survival (PFS) per RECIST 1.1 by blinded independent central review (BICR) in participants with PD-L1 expression in [redacted]
• Overall survival (OS) in participants with PD-L1 expression in [redacted]

Secondary outcome

Not applicable.

Study description

Background summary

RD006691 study is a multicenter interventional clinical performance study with an In-vitro Diagnostic Device (IVD) , more specifically a Companion Diagnostic Device (CDx), not using only leftover samples. The IVD will be used
to support patient screening for a pharmaceutical clinical trial that is running in parallel sponsored by pharma partner [redacted]). The performance study falls under IVDR article 58(2) sentence 1 and therefore falls under the same requirements as IVDR article 58(1a,b). Fresh biopsy samples will be used for this performance study.
The IVD *VENTANA PD-L1 (SP263) CDx Assay* (Class C IVD) is a qualitative immunohistochemical assay that determines the expression levels of programmed death ligand 1 (PD-L1) protein; it is indicated as an aid in identifying patients with non-small cell lung cancer (NSCLC) who may benefit from treatment with PD-L1 targeted therapy in combination regimens ([redacted]), under the above-referred pharmaceutical trial. The device bears the CE mark.

Tumor specimens from approximately [redacted] patients undergoing screening under the pharmaceutical trial will be stained with *VENTANA PD-L1 (SP263) CDx Assay* at diagnostic

(Dx) testing sites. Stained slides from each case will be interpreted by a qualified pathologist who will assign a PD-L1 IHC expression level at the [redacted]. Efficacy results from the pharmaceutical study will be used to evaluate the clinical performance of *VENTANA PD-L1 (SP263) CDx Assay* as a CDx device to identify patients with locally advanced, unresectable or metastatic NSCLC who may benefit from first line treatment with [redacted].

Study objective

The objective of this study is to establish the clinical performance of VENTANA PD-L1 (SP263) CDx Assay as a companion diagnostic (CDx) for the identification of patients with NSCLC who may benefit from treatment with
[redacted].
This clinical performance study protocol is being conducted in support of the [redacted] Study to determine the PD-L1 expression level of tumor specimens submitted for [redacted] Study enrollment screening. PD-L1
expression level will be ussd for patient selection, stratification and study endpoint analyses in the [redacted] Study. Efficacy results from the [redacted] Study may serve as the basis for establishing the clinical performance of VENTANA PD-L1 (SP263) CDx Assay.

Study design

The current state of the art in medicine and/or diagnosis for patients with NSCLC includes IHC testing for PD-L1 expression to inform the appropriate course of treatment. Several PD-(L)1 inhibitors are currently approved by the FDA and EMA in first-line, PD-L1 high ([redacted]) NSCLC patients who are negative for actionable molecular biomarkers. Despite the benefits of PD-(L)1 inhibitors, more than half of patients with NSCLC do not respond to first line anti-PD-(L)1 therapy and most participants who do respond will typically progress within a year. Investigating treatment modalities that incorporate combinations of agents targeting different pathways in combination, including [redacted], within the immune cascade has the potential to provide additional
benefit beyond that of PD-1 inhibition alone. (For a detailed discussion of the current standard of care for NSCLC patients and PD-L1/PD-1 blocking antibodies, [redacted])

As part of a co-development paradigm including both an investigational therapy and an investigational in vitro diagnostic (IVD) device, RTD, as the IVD device manufacturer and Sponsor of the clinical performance study for the IVD device, will be responsible for certain aspects of the investigational IVD device use within the [redacted] Study. As such, this Dx protocol supports the [redacted] Study by describing the procedures for how the patient samples that are collected as part of the [redacted] Study should be tested with the investigational VENTANA PD-L1 (SP263) CDx Assay at the Dx testing sites. The investigational VENTANA PD-L1 (SP263) CDx Assay will be used to determine PD-L1 IHC expression level of NSCLC tumor specimens collected from patients who are being screened for enrollment into the [redacted] Study.

It is anticipated that tumor specimens from approximately [redacted] patients undergoing screening to participate in the [redacted] Study will be stained with VENTANA PD-L1 (SP263)

CDx Assay at Dx testing sites. Stained slides from each case will be interpreted by a qualified pathologist who will assign a PD-L1 IHC expression level at the [redacted]. Cases will be stained and evaluated with VENTANA PD-L1 (SP263) CDx Assay at the Dx testing site(s) in the approximate order in which they are received.
Participants must have a PD-L1 expression level of [redacted] per central laboratory to be eligible for the [redacted] Study. PD-L1 expression level at the [redacted] cutoff ([redacted]) will be one of the stratification factors for randomization to treatment arms. Primary endpoints are progression-free survival (PFS) and overall survival (OS) in participants with PD-L1 [redacted].
Efficacy results from the [redacted] Study will be used to evaluate the clinical performance of VENTANA PD-L1 (SP263) CDx Assay as a CDx device to identify patients with locally advanced, unresectable or metastatic NSCLC who may benefit from first line treatment with [redacted].

Intervention

Lung biopsies will be obtained in the framework of the pharmaceutical study.

Study burden and risks

Collection of tissue biopsy samples is considered part of standard clinical practice to determine the most appropriate therapeutic option for NSCLC patients. The possible complications of lung biopsies include Blood loss or blood clots, pain or discomfort, infection, pneumonia, pneumothorax and bleeding from the lung. In addition, there may be risks during the biopsy such as dizziness, localized mild pain, pressure or pain from the needle, soreness or tenderness at the biopsy site, swelling or redness and scarring at the biopsy site. In rare cases, you may develop an infection. Other unforeseen risks may occur.

There is also the risk of a false positive or false negative test result. In the event of a false negative result, the patient may not have the opportunity to receive a potential benefit from the investigational therapy but would
discuss alternative treatment with their doctor. In addition, a false positive result from the assay (i.e., incorrect assignment of a PD-L1 expression level [redacted]) could lead to enrollment of a patient who would otherwise have been excluded. In that event, the patient may be subjected to potential negative side effects of the treatment received in the context of the trial.

There are also the risks associated with patient data privacy (possible breach in patient confidentiality).

Contacts

Scientific

Ventana Medical Systems, Inc. (Roche Tissue Diagnostics or “RTD”)
HD Damasco
Innovation Park Drive 1910 E
Tucson 85755 AZ
United States
+13174536750
Public
Ventana Medical Systems, Inc. (Roche Tissue Diagnostics or “RTD”)
HD Damasco
Innovation Park Drive 1910 E
Tucson 85755 AZ
United States
+13174536750

Trial sites

Trial sites in the Netherlands

HagaZiekenhuis
Target size: 2

Noordwest Ziekenhuisgroep
Target size: 2

Zuyderland
Target size: 2

Medisch Spectrum Twente
Target size: 2

Franciscus
Target size: 2

Listed location countries

Belgium, Brazil, France, India, Turkey, South Korea, Philippines, Slovenia, Norway, Argentina, Canada, China, Estonia, Finland, Greece, Portugal, Thailand, Romania, Slovakia, Bulgaria, Germany, Croatia, Japan, Italy, Netherlands, Poland, Spain, Taiwan, Czech Republic, United States, Panama, Serbia, Hungary, Mexico, Singapore, Sweden

Eligibility criteria

Age
Adolescents (16-17 years)
Elderly (65 years and older)

Adults (18-64 years)

Inclusion criteria

To be included in this Dx protocol, a specimen must meet all of the following criteria:
1. It must be a formalin-fixed, paraffin embedded (FFPE) tumor specimen submitted for central PD-L1 testing for the [redacted] Study and processed in accordance with standard practice;
2. It must contain sufficient tumor 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 the Dx protocol if any of the following criteria are true:
1. It is known to be fixed in 95% alcohol, alcohol-formalin-acetic acid (AFA), or PREFER;
2. It is a fine needle aspirate (FNA), cytology, bone marrow or bone specimen;
3. It consists of tissue containing bone that has been decalcified*; or
4. Cut slides were prepared more than 12 months prior to staining.
*Prior to testing any specimen, evidence of decalcification must be obtained. This information may be obtained from the pathology report. If the pathology report is not available or does not specify whether the sample was decalcified or not, the sample must be held and the submitting site queried. If the sample has been decalcified, testing cannot proceed.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	01-09-2024
Enrollment:	10
Duration:	16 months (per patient)
Type:	Actual

WORLD

Recruitment status:	Recruitment started
Start date (anticipated):	02-07-2024
Enrollment:	1600
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	Ventana PD-L1 (SP263) CDx Assay
Registration:	No

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Approved WMO

Date:	30-08-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	05-02-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-03-2025
Application type:	Amendment
Review commission:	METC LDD

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	NL86936.000.24
Research portal	NL-005153