Clinical Performance Study Protocol for Use of VENTANA PD-L1 (SP263) CDx Assay for Determining PD-L1 Status in Genmab Phase 3 Trial GCT1046-06

Published: 17-01-2025
Last updated: 31-01-2025

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

Summary

ID

NL-OMON57246

Source
ToetsingOnline

Brief title
Diagnostics Protocol for CDx Assay in Study GCT1046-06

Condition

- Other condition

Synonym
Lung Cancer, Metastatic Non-Small Cell Lung Cancer

Health condition

Oncology - Non-Small Cell Lung Cancer

Research involving

Human

Sponsors and support

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

Intervention

Keyword: N/A

Outcome measures

Primary outcome

Primary Endpoint:

The primary endpoint for the clinical performance study is the primary efficacy endpoint defined in the Study GCT1046-06 protocol: overall survival (OS).

Primary Acceptance Criteria:

The clinical performance of VENTANA PD-L1 (SP263) CDx Assay will be considered acceptable if the primary efficacy analysis of OS in the Study GCT1046-06 supports the efficacy of acasunlimab (GEN1046) in combination with pembrolizumab treatment in the population selected using the assay.

Secondary outcome

Additional Endpoints:

Additional endpoints for this study include the following staining performance measures of the VENTANA PD-L1 (SP263) CDx Assay:

- Initial and final staining acceptability rates for the assay

- Initial and final tissue morphology acceptability rates for the assay

- Initial and final background acceptability rates for the assay

There are no pre-determined acceptance criteria associated with these

additional endpoints.

Study description

Background summary

VENTANA PD-L1 (SP263) CDx Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP263 intended for laboratory use in the assessment of programmed death ligand 1 (PD-L1) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue specimens by light microscopy.
The VENTANA PD-L1 (SP263) CDx Assay is used with the OptiView DAB IHC Detection Kit for staining on a BenchMark IHC/ISH instrument.
VENTANA PD-L1 (SP263) CDx Assay is indicated as an aid in identifying NSCLC patients who may benefit from treatment with acasunlimab in combination with pembrolizumab.
Results of the VENTANA PD-L1 (SP263) CDx Assay should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.
CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

Study objective

The objective of this study is to demonstrate the clinical performance of VENTANA PD-L1 (SP263) CDx Assay in terms of its ability to identify patients with metastatic NSCLC who may benefit from treatment with acasunlimab (GEN1046) in combination with pembrolizumab after treatment with a PD-1/PD-L1 inhibitor and platinum-containing chemotherapy.

Study design

This clinical performance study follows a combined trial approach, in which the efficacy and safety of treatment with acasunlimab (GEN1046) in combination with pembrolizumab and the clinical performance of the investigational VENTANA PD-L1 (SP263) CDx Assay will be evaluated simultaneously.

Intervention

lung biopsies will be obtained as part of the pharmaceutical study (in case no archived sample is available)

Study burden and risks

Taking tissue biopsy samples is considered part of standard clinical practice to determine the most appropriate therapeutic option for NSCLC patients. Potential complications of a lung biopsy include blood loss or blood clots, pain or discomfort, infection, pneumonia, collapsed lung, and bleeding from the lung. In addition, there may be risks during the biopsy such as dizziness, mild local pain, pressure or pain from the needle, pain 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 a risk of a false positive or false negative test result. In the case of a false negative result, the patient may not have the opportunity to receive a potential benefit from the study therapy, but may discuss alternative treatment with their doctor. In addition, a false positive test result (i.e., incorrect assignment of a PD-L1 expression level >= 50% TC) may lead to enrollment of a patient who would otherwise have been excluded. In this case, the patient may be exposed to potential adverse side effects of the treatment received in the study.

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

To be eligible for staining with the VENTANA PD-L1 (SP263) CDx Assay in this diagnostic
study, a specimen must meet all of the following criteria:
1. It must be a formalin-fixed, paraffin-embedded (FFPE) NSCLC tumor specimen submitted for Study GCT1046-06 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 staining with the VENTANA PD-L1 (SP263) CDx Assay
in this diagnostic study based on any of the following:
1. It is known to be fixed in 95% alcohol or other alcohol-based fixative, alcohol-formalinacetic
acid (AFA), or PREFER;
2. It is a fine needle aspirate (FNA) or cytology 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.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-01-2025
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	VENTANA PD-L1 (SP263) CDx-assay
Registration:	No

Ethics review

Approved WMO

Date:	17-01-2025
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
CCMO	NL87815.000.24