An open-label, multi-center rollover protocol for continued characterization of safety and tolerability for subjects who have participated in a Novartis-sponsored spartalizumab study as single agent or in combination with other study treatments

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The purpose of this study is to allow collection of safety and tolerability data in subjects benefitting from treatment with spartalizumab as a single agent or in combination with other study treatments in a pre-defined (Appendix Section 16.1)...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51829

Source
ToetsingOnline

Brief title
CPDR001X2X01B

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

solid cancer(s); malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (sponsor/verrichter van dit onderzoek)

Intervention

Keyword: PDR001, roll-over, safety, spartalizumab

Outcome measures

Primary outcome

To collect safety and tolerability data for spartalizumab as single agent or in

combination with other study treatments

Secondary outcome

To allow subjects enrolled in a spartalizumab Novartis-sponsored study

continued access to study treatment

Study description

Background summary

Spartalizumab is a high-affinity, ligand-blocking, humanized anti-programmed death-1 (PD-1) IgG4 antibody that blocks the binding of Programmed death-ligand 1 (PD-L1) and programmed death-ligand 2 (PD-L2) to PD-1. Spartalizumab recognizes PD-1 in cynomolgus monkeys and shows functional activity in vitro/ex vivo. For further details, please refer to (spartalizumab Investigator*s Brochure).

Study objective

The purpose of this study is to allow collection of safety and tolerability data in subjects benefitting from treatment with spartalizumab as a single agent or in combination with other study treatments in a pre-defined (Appendix

Section 16.1) Novartis-sponsored spartalizumab study that has reached its primary objective(s) and the requirements for writing the primary CSR, or has been terminated for other reasons.

Study design

Multi-level, open label roll-over study. Eligible parent protocols are listed in appendix section 16.1 of the protocol.

Intervention

Study treatment is defined as spartalizumab as monotherapy or in combination with other treatments intended to treat cancer, as defined in the parent protocol.

Study burden and risks

Risks: possible side-effect of PDR001 and/or study drugs used in combination. Risks and discomforts associated with the study assessments like blood sampling and CT-scans.

Burden: 1 visit every 4 weeks during which various study assessments are performed. This might be physical exams, blooddraws and a CT-scan or a radiology assessment to determine if progression of disease.

Contacts

Public
Novartis

Haaksbergweg 16
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NL
Scientific
Novartis

Haaksbergweg 16
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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. Signed informed consent must be obtained prior to participation in the study.
2. Subject is currently enrolled in a pre-defined Novartis-sponsored study and is receiving
spartalizumab as single agent or in combination with other study treatment.
3. Subject is currently deriving clinical benefit from the study treatment, as determined by the
investigator.
4. Subject has demonstrated compliance, as assessed by the investigator, with the parent
protocol requirements.
5. Subject is willing and able to comply with the scheduled visits and treatment plans.

Exclusion criteria

Subject has been permanently discontinued from spartalizumab in the parent protocol for any reason other than enrollment in the CPDR001X2X01B study.
Subject does not meet the criteria specified in the parent protocol criteria for continued study treatment.
Subject not willing to comply with the contraception requirements outlined in the exclusion criteria of the parent protocol.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-08-2022
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Sabatolimab
Generic name:	Sabatolimab
Product type:	Medicine
Brand name:	spartalizumab
Generic name:	spartalizumab

Ethics review

Approved WMO

Date:	11-05-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	15-07-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	13-08-2022

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	11-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	09-12-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	23-12-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	13-01-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	03-02-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	07-08-2023

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	31-08-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
EudraCT	EUCTR2019-000508-14-NL
CCMO	NL80782.058.22