HLA-A*02 TESTING USING ONE LAMBDA*S SECORE CDX HLA SEQUENCING SYSTEM IN DAIICHI SANKYO*S FIRST-IN-HUMAN STUDY OF DS-2243a IN PARTICIPANTS WITH ADVANCED SOLID TUMORS

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON57350

Source
ToetsingOnline

Brief title
CPSP FOR THE SECORE CDX HLA SEQUENCING SYSTEM FOR DS2243-054

Condition

- Other condition

Synonym
cancer, tumour

Health condition

Oncology

Research involving
Human

Sponsors and support

Primary sponsor: One Lambda, inc
Source(s) of monetary or material Support: One Lambda;inc

Intervention

Keyword: HLA-A*02, SEQUENCING SYSTEM, TUMORS

Outcome measures

Primary outcome

The Device Clinical Performance Study primary endpoints is the detecting HLA-A Locus Target Alleles and distinguishing Target Alleles from other HLA-A genotypes to select participants for eligibility to receive treatment under the medicinal product clinical study. The performance of the Device for performance evaluation will be assessed based on the primary endpoints described in the medicinal product clinical study protocol (DS2243-054).

A brief summary of the primary endpoints described in the medicinal product clinical study protocol is provided below:

1. Dose Escalation (Part 1): The primary endpoints of the Dose Escalation Part are dose limiting toxicity, treatment-emergent adverse event (TEAE), and other safety parameters.

2. Dose Expansion (Part 2):

• Safety - The primary safety endpoints of the Dose Expansion Part are TEAEs and other safety parameters.

• Efficacy - The primary efficacy endpoint of the Dose Expansion Part is overall response rate (ORR).

The Device for performance evaluation will be used in this Clinical Performance Study as an aid in the determination of eligibility for enrollment in the medicinal product clinical study for patients diagnosed with advanced SS or MRCLS as well as metastatic or unresectable locally advanced NSCLC (Ad/Sq) or UC through the extraction of patient DNA from whole blood followed by PCR amplification of the target alleles and HLA-A genomic sequencing.

Secondary outcome

There are no key secondary endpoints for this clinical performance study.

Study description

Background summary

This Clinical Performance Study is defined as an interventional performance study per Article 2 (46) Regulation (EU) 2017/746. The investigational SeCore* CDx HLA Sequencing System (henceforth referred to as the Device) will be used to provide human leukocyte antigen (HLA) allele test results to aid in the eligibility determination of patients associated with the interventional medicinal product clinical trial DS2243-054. Minimally invasive specimen collection via venipuncture is performed for the purpose of this Clinical Performance Study

Study objective

The primary objective of this Clinical Performance Study is to utilize the Device for performance evaluation to detect HLA-A Locus alleles as part of the eligibility criteria for patients to receive an experimental medicinal product under the DS2243-054 first in human clinical trial.

The Device for performance evaluation will be used to directly sequence DNA samples purified from collected Whole Blood specimens to specifically detect

Target Alleles, HLA-A*02:01, A*02:02, A*02:03, A*02:04, A*02:05, A*02:06, A*02:09, A*02:10, or A*02:11, in patients diagnosed with advanced (metastatic or unresectable) SS or MRCLS as well as metastatic or unresectable locally advanced Adenocarcinoma/Squamous cell carcinoma type NSCLC (Ad/Sq) or Urothelial Carcinoma (UC).

The safety and efficacy clinical performance characteristics of the Device for performance evaluation used in this study are evaluated based on the endpoint of the corresponding medicinal product clinical trial.

The secondary objectives of this Clinical Performance Study are to conduct the following exploratory evaluations and develop descriptive statistics on the following attributes:
• Operational characteristics of the Device for performance in a clinical study setting.
• Determine prevalence of the Target Alleles in the participant population.
• Gather feedback on the implementation of the Device for performance evaluation from DSI.

Study design

The Clinical Performance Study involves the HLA testing of prospective venipuncture whole blood specimen collection under the DS2243-054 medicinal product clinical trial protocol from consented patients, who are at least 18 years of age diagnosed with advanced (metastatic or unresectable) SS, MRCLS as well as metastatic or unresectable locally advanced NSCLC Ad/Sq or UC. Patient recruitment, specimen collection, and shipment will occur at and be managed by approximately five DSI investigator sites within the USA and European Union participating in the DS-2243-054 clinical trial. As DSI intends to enroll approximately 150 participants into the medicinal product clinical trial, the expected overall screening sample size should be approximately 650 patients.

Upon receipt of the specimen at the One Lambda Inc.*s internal investigator testing site, specimen accessioning, processing into DNA, and sample testing will be managed and conducted by the testing site. DNA sample testing to determine patient HLA Target Allele status will be performed using the investigational and performance evaluation use only Device.

The HLA test results will be generated by the Device and reported back to DSI and their investigator sites for continued patient eligibility determination for the DS2243-054 medicinal product clinical trial.

Study burden and risks

Please refer to the protocol.

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

Specimens collected from patients consented by DSI*s investigator sites.
Specimen collection kit contains complete and accurate paperwork. If the paperwork is not complete and/or accurate and remediation can be performed.
Specimens provided by DSI investigator sites will meet collection and quality specifications per the Device IFU.

Exclusion criteria

Specimens collected from patients not consented.
Insufficient specimen quantity for testing.
Specimen type not specified in this protocol.

Specimen receptacle not specified in this protocol.
Specimen collection kit does not contain complete and accurate paperwork to sufficiently identify the specimen, and remediation is unable to be performed.
Specimens which are received in an inappropriate condition (see SeCore* CDx HLA Sequencing System, TDX-OLI-DMR-PS-3132-6).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	37
Type:	Anticipated

Medical products/devices used

Generic name:	SeCore CDx HLA Sequencing System
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	27-02-2025
Application type:	First submission
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
Other	2024-A01893-44
CCMO	NL87812.000.24