Long-term follow-up of pediatric patients exposed to nivolumab + relatlimab fixed-dose combination (FDC) enrolled in the Dutch Melanoma Treatment Registry (DMTR) (CA224-122)

First published: 13/12/2023

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Study | Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107907

EU PAS number

EUPAS107906

Study ID

107907

DARWIN EU® study

No

Study countries

Netherlands

Study description

This post-authorization safety study (PASS) will collect long-term follow-up data in pediatric patients exposed to nivolumab + relatlimab fixed-dose combination, and is part of EMA approved European Union (EU) Risk Management Plan. Data will be collected through the Dutch Melanoma Treatment Registry

Study status

Planned

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

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Institution

Networks

Dutch Melanoma Treatment Registry (DMTR)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elise Roy

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/02/2024

Study start date

Planned: 30/06/2025

Data analysis start date

Planned: 30/06/2025

Date of interim report, if expected

Planned: 31/12/2026

Date of final study report

Planned: 31/12/2038

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

The main objective is to evaluate Grade 3 to 4 adverse drug reactions (including immune-related adverse reactions) experienced by pediatric patients treated with nivolumab + relatlimab FDC, and their management.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OPDUALAG

Population studied

Age groups

Adolescents (12 to < 18 years)

Estimated number of subjects

20

Study design details

Outcomes

Number of participants with Frequency of Grade 3 to 4 adverse drug reactions (ADRs) as assessed by the Common Terminology Criteria for Adverse Events (Version 6) criteria ADR management, Participant baseline demographic, comorbidities, disease characteristics, treatment history Dose levels and frequency of nivolumab+relatlimab (nivo+rela) FDC treatment Number of nivo+rela FDC treatment infusions Number of participants with nivo+rela FDC treatment dose interruptions or discontinuations, subsequent therapies, or growth/development disorders Overall survival Time to progression

Data analysis plan

A detailed Statistical Analysis Plan will be developed for this study. General descriptive statistics will include mean, median, minimum, maximum, and standard deviation for continuous variables, count and percentages will be used to examine categorical variables. The time to event endpoint will be analyzed according to the Kaplan-Meier method, as data allow. Data from all patients who receive at least 1 dose of treatment will be analyzed. The treated set is defined as all patients enrolled in the registry and meeting the study eligibility criteria and receiving at least 1 dose of treatment. The data collected at baseline will be used to characterize the population. Descriptive statistics will be provided to assess demographic information, disease characteristics and other clinical characteristics, and treatment history.

Data management

Data sources

Data source(s), other

DMTR Netherlands

Data sources (types)

Other

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No