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)

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## Administrative details

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

## Elise Roy ctt.group@bms.com

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

#### **Medicinal product name**

**OPDUALAG** 

# Population studied

#### Age groups

Adolescents (12 to < 18 years)</li>

#### **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

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

Data source(s), other

**DMTR Netherlands** 

#### Data sources (types)

# 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