

# A Prospective, Non-interventional, Observational Post-authorisation Study to Assess the Late-effects of Patients who have received Unituxin (ALIVIO)

**First published:** 22/07/2016

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/17796>

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### **EU PAS number**

EUPAS14095

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### **Study ID**

17796

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### **DARWIN EU® study**

No

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### Study countries

- France
  - Germany
  - Italy
  - Netherlands
  - Norway
  - Spain
  - United Kingdom
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### Study description

Following assessment of the global availability of Unituxin, UTC has decided to terminate the trial due to significant short and intermediate-term drug supply shortages. The study has been terminated on 15 December 2016. Please also note, no data was collected as per section 3, only planned dates have been populated in the actual dates field due to restrictions on the form.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### United BioSource Corporation (UBC)

- Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

Institution

Non-Pharmaceutical company

ENCePP partner

Multiple centres: 40 centres are involved in the study

## Contact details

### Study institution contact

Alessandra Pranzo

Study contact

[druginformationUTEL@unither.com](mailto:druginformationUTEL@unither.com)

### Primary lead investigator

Janine Collins

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 28/04/2016

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### Study start date

Planned: 02/01/2017

Actual: 15/12/2016

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### Date of final study report

Planned: 11/03/2030

Actual: 15/12/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

United Therapeutics Corporation (UTC)

## Study protocol

[DIV-NB-402 Final Protocol Version 2.0\\_16Aug2016.pdf\(4.06 MB\)](#)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness  
Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To evaluate the late-effects associated with the central and peripheral nervous system, growth and endocrine development, auditory, visual, hepatic, renal, lower urinary tract, cardiac, respiratory, skeletal, second and secondary malignancies in patients who received Unituxin for neuroblastoma and remain event-free for at least 5 years since the start of Unituxin immunotherapy.

## Study Design

**Non-interventional study design**

Cohort  
Other

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**Non-interventional study design, other**

Prospective, observational cohort registry

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L01XC16) dinutuximab beta

dinutuximab beta

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**Medical condition to be studied**

Neuroblastoma

## Population studied

**Short description of the study population**

High-risk neuroblastoma patient for whom a decision has been made to commence Unituxin immunotherapy.

Patients who are participating in study DIV-NB-401, a Post-marketing Study to Further Assess the Immunogenicity and Safety of Unituxin in High-Risk Neuroblastoma Patients were also eligible to participate in this study.

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**Age groups**

Infants and toddlers (28 days - 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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**Special population of interest**

Other

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**Special population of interest, other**

Neuroblastoma patients

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**Estimated number of subjects**

590

## Study design details

## **Outcomes**

The late effects associated with the relevant systems and second/secondary malignancies will be analysed in the Safety Set of patients by comparing the characteristics at 12 months to 5 years to the characteristics at baseline using descriptive statistics. Event-free survival (EFS) and Overall Survival (OS) will be assessed every 6 months for up to 5 years following treatment. EFS will be calculated as the time from start of Unituxin until the first occurrence of the events of relapse, PD, secondary malignancy, or death. If no event occurs, the date of last contact will be used. OS will be calculated as the time from start Unituxin until death.

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## **Data analysis plan**

All analyses will be performed using SAS for Windows statistical software using validated implementations of each application or SAS custom programming. The data from all centres will be combined, so that an adequate number of patients will be available for analyses. Summary tabulations will be presented that will display the number of observations, mean, standard deviation, median, minimum and maximum for continuous variables, and the number and percentage per category for categorical or ordered categorical data. In addition, two sided 95% confidence intervals will be calculated for all outcomes when possible.

## **Data management**

### **Data sources**

## **Data sources (types)**

Other

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### **Data sources (types), other**

Prospective patient-based data collection, Case report forms will be designed to gather data from the medical records

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation



## **Data characterisation conducted**

Unknown