Physician Survey to Assess the Effectiveness of the Additional Risk Minimisation Measures (aRMM) for KIMMTRAK® (tebentafusp) (IMCR-0001)

First published: 12/12/2023

Last updated: 12/12/2023

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107980

EU PAS number

EUPAS107979

Study ID

107980

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Poland

Study description

The aRMM for KIMMTRAK include a Treatment Guide for Healthcare Professionals and a Patient Guide. These materials are distributed to all physicians who are expected to prescribe KIMMTRAK. The purpose of the Treatment Guide for Healthcare Professionals is to highlight the key measures for minimising the severity of cytokine release syndrome (CRS) associated with KIMMTRAK use. Healthcare professionals are required to provide the Patient Guide to patients when KIMMTRAK is prescribed in order that patients are informed as to what to expect following their KIMMTRAK infusion. The proposed assessment will evaluate the physicians' understanding of the important safety information in the Treatment Guide for Healthcare Professionals and whether healthcare professionals are providing patients with the Patient Guide.

Study status

Ongoing

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Peter Psarologos

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 08/08/2023

Study start date
Actual: 05/12/2023

Date of final study report
Planned: 15/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Immunocore Ireland Ltd.

Study protocol

Physician_survey_Kimmtrak_RMP_v_3.0_09Nov2023.pdf(1.45 MB)

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:

Physicians’ understanding of the important safety information detailed in the Treatment Guide for Healthcare Professionals to minimise the severity of CRS with KIMMTRAK.

Study Design

Non-interventional study design

Cross-sectional

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

250

Study design details

Outcomes

This study will assess the following: a) Physicians’ understanding of the important safety information detailed in the Treatment Guide for Healthcare Professionals to minimise the severity of CRS with KIMMTRAK. b) Healthcare

professionals’ distribution of the Patient Guide to patients treated with KIMMTRAK.

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for responses to questions that address the survey objectives (i.e. excluding demographic questions). Survey data will be analysed overall and stratified by country. Responses will be categorised as “Correct response” and “Incorrect response”.

Data management

Data sources

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