Cross-sectional study to assess the effectiveness of the patients’ alert card to inform on the risk of differentiation syndrome in AML patients treated with TIBSOVO® (Ivosidenib) (IMPACTA)

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Study | Ongoing

Administrative details

EU PAS number

EUPAS1000000190

Study ID

1000000190

DARWIN EU® study

No

Study countries

Austria

Belgium

France

Germany

Greece

Poland

Study description

A Patient Alert Card (PAC) is part of an additional risk minimization measure for differentiation syndrome in acute myeloid leukemia (AML) indication, focusing on the key elements to alert patients on the symptoms of differentiation syndrome and the importance of seeking medical advice. The PAC will be distributed inside each pack of ivosidenib.

A dedicated study for measuring effectiveness of additional risk minimisation measures on differentiation syndrome (PAC) will be conducted. This study will be classified as a Post-Authorisation Safety Study (PASS) and will follow the European (EU) Good Pharmacovigilance Practices (GVP) Module XVI and VIII guidelines.

Study status

Ongoing

Research institutions and networks

Institutions

Institut de Recherches Internationales Servier

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Institution

Contact details

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Primary lead investigator

Mehdi KERTOUS

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/07/2023

Actual: 18/07/2023

Study start date

Planned: 31/10/2026

Actual: 25/04/2024

Data analysis start date

Planned: 31/05/2028

Date of final study report

Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Institut de Recherches Internationales Servier

Study protocol

IMPACTA_Protocol_signed v4_0_FINAL_20260113 (1).pdf (1.13 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

This study will be a multi-national, observational cross-sectional survey among adult patients who have recently received TIBSOVO® (Ivosidenib) for treatment of AML, that will be conducted in at least three countries in the European Union (EU).

Main study objective:

The study will evaluate the effectiveness of the PACs to inform on the risk of differentiation syndrome in AML patients treated with TIBSOVO® (Ivosidenib), using process dimensions for patients' awareness, receipt of the material, reading, utility of the PAC, self-reported behaviour, and knowledge.

Primary Objective

To assess the effectiveness of the PAC on DS in AML patients treated by TIBSOVO®, i.e., to assess the awareness of the PAC and the knowledge about DS.

Secondary Objective

To assess receipt, reading, utility, and self-reported behaviour related to the PAC by AML patients treated with TIBSOVO® (ivosidenib).

Exploratory Objective

To assess the global informative value of the PAC regarding DS in AML patients treated by TIBSOVO®, i.e., to assess collectively all dimensions of the PAC: awareness, knowledge, receipt, reading, utility and self-reported behaviour.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

TIBSOVO

Study drug International non-proprietary name (INN) or common name

IVOSIDENIB

Anatomical Therapeutic Chemical (ATC) code

(L01XM02) ivosidenib

ivosidenib

Medical condition to be studied

Acute myeloid leukaemia

Population studied

Short description of the study population

Patients will be identified through their Healthcare Professionals (HCPs) – (physicians and nurses) and will be included in the study if they are aged ≥18 years at recruitment, have taken Ivosidenib for newly diagnosed AML in the previous 6 months, and are able to understand and complete the consent form and patient survey.

Participant selection will be based on systematic sampling, i.e., all consecutive eligible participants are expected to be included in the study, with no selection other than the eligibility criteria and the study period defined.

Physicians will be identified using the lists of AML specialists provided by the Marketing Authorisation Holder. A pilot step will be conducted to determine the feasibility of recruitment and the participants/Healthcare professionals (HCPs) ratio to be used in the study.

Estimated number of subjects

66

Study design details

Setting

The survey will collect data resulting from the PAC of TIBSOVO®, referring in particular to the patient’s receipt, the understanding of DS risk, the correct identification of these symptoms onset and the knowledge of the right actions to be taken. Data for this study will be collected exclusively through a participant self-administered paper

survey. No additional clinical data will be collected, and no medical record review, or

interventional procedures will be performed as part of this study.

Inclusion criteria

Patients will be included if they meet all the following criteria:

1. Adult patients (female and male) aged ≥18 years at the time of recruitment.
2. Who started TIBSOVO® for newly diagnosed AML within the last 6 months at their physician discretion, and have been treated with TIBSOVO® prior to enrolment in the study, whether or not still receiving TIBSOVO® at the time of recruitment.
3. Able to understand and provide written informed consent, including permission to share their responses in aggregate with the EMA or national competent authorities (CA), if requested.
4. Able to read and understand in native language of each of the participating countries, and willing to complete the patient survey.

Exclusion criteria

1. Patients who declared having participated in user testing for this study.

Outcomes

Primary outcome

• Number of participants having at least 80% of understanding rate from pooled questions comprising awareness and knowledge items, for primary respondents and completers.

Secondary outcome

• Number of participants having at least 80% of understanding rate from pooled questions comprising receipt, reading, utility and self-behaviour dimensions, for secondary respondents and completers.

Exploratory outcome

• Number of participants (completers) having at least 80% understanding rate

in the pooled primary and secondary scores.

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Frequency distributions will be calculated for items that address the survey objective (excluding demographic questions).

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

Structured, self-administered questionnaire comprising closed-ended questions or statements with multiple response choices will be used to collect the survey data. A user testing evaluation will be conducted prior to the master study.

Data sources (types)

Patient surveys

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