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

PURI

https://redirect.ema.europa.eu/resource/1000000190

EU PAS number

EUPAS1000000190

Study ID

1000000190

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Netherlands

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

Study institution contact

Laurence Leber

Study contact

Global.RWE.Dept@servier.com

Primary lead investigator

Nadjat Mounedji

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/07/2023

Actual: 18/07/2023

Study start date

Planned: 09/11/2023

Actual: 25/04/2024

Date of final study report

Planned: 30/05/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Institut de Recherches Internationales Servier

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:

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

Name of medicine

TIBSOVO

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

IVOSIDENIB

Anatomical Therapeutic Chemical (ATC) code

(L01XX62) 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.

Patient selection will be based on systematic sampling, i.e., all consecutive eligible patients 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. The decision about site participation in the master study will be based on the site's interest in participating, the availability of staff to manage the study, and the identification of at least 2 potential patients for inclusion in the study. Nurses will be identified through physicians.

Estimated number of subjects

133

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. Additionally, the survey will collect information on demographic characteristics of patients including age, sex, geographical location, the time under TIBSOVO® treatment, the work or retirement status, known cognitive impairment and any concurrent disease that may impact patient’s cognitive function.

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.

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

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