Prospective, international, non-interventional study to assess the short- and long-term safety and effectiveness of adult patients with relapsed or refractory B cell acute lymphoblastic leukemia receiving Aucatzyl® treatment (AUTO1-LT2)

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Study Planned

Administrative details

EU PAS number

EUPAS1000001004

Study ID

1000001004

DARWIN EU® study

No

Study countries

European Union

United States

Study description

This is a prospective international, non-interventional study to evaluate the safety (including secondary malignancies) and effectiveness of adult patients with r/r B ALL receiving Aucatzyl treatment in the post marketing setting.
The purpose of this study is to characterize the short- and long-term safety profile of Aucatzyl® (obecabtagene autoleucel; obe-cel) in the post-marketing setting, including the important identified risks and potential risks associated with this product. Aucatzyl is a cell-based therapy product consisting of autologous enriched T cells that are transduced with a lentiviral vector to express an anti-CD19 (CAT) CAR. This study will make secondary use of data collected from patients included in the EBMT and the CIBMTR cellular therapy registries.

Study status

Planned

Contact details

Study institution contact

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Study contact

medinfo.europe@autolus.com

Primary lead investigator

Samantha Jaglowski

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/07/2025

Actual: 18/11/2025

Study start date
Planned: 30/07/2025

Date of final study report
Planned: 30/06/2045

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Autolus Limited

Regulatory

Was the study required by a regulatory body?

Yes

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

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

Regulatory procedure number

EMEA/H/C/005907/0000

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This study will use secondary data from the EBMT and CIBMTR cellular therapies registry and will include data from patients who have been treated with Aucatzyl in the post approval setting.

Main study objective:

To characterize the short- and long-term safety of Aucatzyl (in the treatment of r/r B ALL). Specifically, the rates and severity (where applicable) of the following AEs:

• CRS, including HLH/MAS.
• ICANS.
• Prolonged cytopenia.
• Hypogammaglobulinemia.
• Clinically significant infections.
• Secondary malignancies.
• Other neurologic toxicities.

• TLS.
• Immunogenicity, defined as hypersensitivity reactions.
• Aggravation of GvHD.
• New occurrence of an autoimmune disorder.
• Overdose.
• Other safety concerns not yet identified in the clinical program.
• To evaluate pregnancy outcomes.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This study will use secondary data from the EBMT and CIBMTR cellular therapies registry and will include data from patients who have been treated with Aucatzyl in the post-approval setting.

Study drug and medical condition

Medicinal product name, other

aucatzyl

obecabtagene autoleucel

Anatomical Therapeutic Chemical (ATC) code

(L01XL12) obecabtagene autoleucel

obecabtagene autoleucel

Medical condition to be studied

Precursor B-lymphoblastic lymphoma refractory

Precursor B-lymphoblastic lymphoma recurrent

Population studied

Short description of the study population

Patients aged 18 and over, diagnosed with r/r B ALL who have been treated with Aucatzyl at participating centers who have consented to share their pseudonymized data with Autolus.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

500

Study design details

Setting

This study will use secondary data from the EBMT and CIBMTR cellular therapies registry and will include data from patients who have been treated with

Aucatzyl in the post approval setting and who consented to share the data with Autolus. This study will follow patients for up to 15 years following Aucatzyl infusion.
Participating centers will enter data directly into the CIBMTR and EBMT databases using electronic case report forms and will follow registry-specific procedures and requirements. The treatment centers will complete the data collection forms per the defined registry schedules. Patients must consent to have their data reported in the registry and to submit pseudonymized data (patient-level data) to Autolus. As this is a non-interventional study, no specific visit schedule is mandated.

Outcomes

For the primary endpoints, the number and percentage of patients who experience at least 1 occurrence of the given event will be summarized for each risk defined in the primary endpoints. The severity will be summarized where applicable, including CRS, ICANS, TLS, and GvHD. Furthermore, annual incidence rates adjusted for follow-up duration will be calculated with the appropriate time periods and methods for relevant risks requiring long-term follow-up (e.g., secondary malignancies).
Time to onset of an AE will be summarized using appropriate methods. Time to onset of long term risks (e.g., any secondary malignancy) will be analyzed using competing risk method with death before experiencing an AE treated as competing event. Competing risk analysis will be performed for secondary malignancies, aggravation of GvHD, and autoimmune disorders.
The analyses of the primary endpoints will be pooled between CIBMTR and EBMT where feasible.
Subgroup analyses may be considered to explore the potential risk factors, including:
• Age categories: ≤ 25 versus 26-54 versus ≥ 55.

• Age category: ≥ 26.
• Patients who receive OOS product.

Data analysis plan

This study seeks to emulate the rigor of a prospective trial while leveraging the extensive RWD collected by the EBMT and CIBMTR registries. By recruiting patients across diverse geographic and clinical settings, the study aims to capture a broad and representative sample of treatment practices and patient outcomes. Endpoint definitions and response harmonization ensure alignment with prospective trial standards, enhancing the study's generalizability and relevance to clinical practice.

The analysis will be performed for all patients who received at least 1 Aucatzyl infusion in this study. The data from EBMT and from CIBMTR will be analyzed separately and combined as appropriate. Categorical data will be summarized by the number and percentage of patients. Continuous data will be summarized using sample size, mean, standard deviation, median, Q1, Q3, minimum, and maximum. Time to event data will be summarized using KM estimators.

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

Center for International Blood and Marrow Transplant Research

European Society for Blood and Marrow Transplantation

Data sources (types)

Other

Data sources (types), other

Stem Cell Transplant Registry

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