

# Lebrikizumab Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS) MotherToBaby Pregnancy Registry (J2T-MC-B005)

**First published:** 17/12/2025

**Last updated:** 17/12/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000608

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### Study ID

1000000608

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### DARWIN EU® study

No

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### Study countries

- ☐ Canada
- ☐ United States
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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Organization of Teratology Information Specialists (OTIS)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

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Study contact

[claudia.salinas@lilly.com](mailto:claudia.salinas@lilly.com)

### Primary lead investigator

Claudia Salinas

Primary lead investigator

# Study timelines

## **Date when funding contract was signed**

Actual: 12/05/2025

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## **Study start date**

Planned: 01/12/2025

Actual: 01/12/2025

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## **Date of final study report**

Planned: 30/06/2036

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

# Study protocol

[LY3650150 B005 NI PASS Protocol Version 2\\_ENCePP\\_Redacted.pdf](#) (1.23 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)?**

Not applicable

# Methodological aspects

**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:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

prospective, observational cohort study of pregnancy and infant outcomes among pregnant women exposed to any dose of lebrikizumab within 5 half-lives prior to the estimated DOC or anytime during pregnancy, enrolled into the OTIS Lebrikizumab Pregnancy Registry

**Main study objective:**

The objective of this study is to assess pregnancy and infant outcomes among women who become pregnant while exposed to lebrikizumab relative to the outcomes in 2 matched comparator populations.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

EBGLYSS

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

LEBRIKIZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(D11AH10) lebrikizumab

lebrikizumab

## Population studied

**Short description of the study population**

The study population includes pregnant women who reside in the US or Canada. The 3 groups of women enrolled and followed for pregnancy and infant outcomes

include:

(1) Pregnant women with AD and who have received at least 1 dose of lebrikizumab

anytime during pregnancy or within 5 half-lives (123 days) prior to the estimated DOC.

(2) Pregnant women with AD exposed to phototherapy or systemic therapy, other than

IL-13-targeting biologics, during pregnancy or within 5 half-lives prior to the estimated DOC (primary comparator).

(3) Pregnant women with AD who may or may not have received treatment for AD but

who have not been exposed to any dose of lebrikizumab, phototherapy, or

systemic

therapy within 5 half-lives prior to the estimated DOC (secondary comparator).

Pregnant women exposed to lebrikizumab who do not meet the eligibility criteria (see

eligibility criteria) of this study may be followed separately as part of an exposure series.

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### **Special population of interest**

Pregnant women

## Study design details

### **Setting**

The registry cohort study will be conducted by the OTIS, which is a network of university- and health department-based telephone information centers serving pregnant women and HCPs throughout North America (Leen-Mitchell et al. 2000).

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### **Outcomes**

The outcomes are major structural defects identified in children up to 1 year of age, as well as rate of spontaneous abortion, elective termination/abortion, stillbirth, preterm delivery, a pattern of minor structural birth defects, small for gestational age at birth, small for age for postnatal growth at 1 year of age, serious infections up to 1 year of age, developmental milestones, and neonatal death.

## 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 sources (types)

[Birth registry](#)

[Electronic healthcare records \(EHR\)](#)

[Patient surveys](#)

## 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