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

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000608

Study ID

1000000608

DARWIN EU® study

No

Study countries

Canada

United States

Study status

Ongoing

Research institutions and networks

Institutions

Organization of Teratology Information Specialists (OTIS)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Claudia Salinas

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 12/05/2025

Study start date
Planned: 01/12/2025

Actual: 01/12/2025

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

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

Not applicable

Methodological aspects

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

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

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

LEBRIKIZUMAB

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.

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).

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown