A Registry Study to Evaluate the Survival and Long-Term Safety of Subjects Who Previously Received Talimogene Laherparepvec in Amgen or BioVEX-Sponsored Clinical Trials

First published: 28/09/2021

Last updated: 30/10/2024

Study Finalised

Administrative details

EU PAS number

EUPAS43115

Study ID

47499

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Canada

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Korea, Republic of
- [ ] Poland
- [ ] Russian Federation
- [ ] South Africa
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

This is an international, multicenter, strictly observational registry program for subjects who have received at least one dose of talimogene laherparepvec on an Amgen or BioVEX-sponsored clinical trial for any tumor type and have ended treatment and participation, including long-term follow-up, in that trial. No experimental intervention is involved. The study will evaluate the overall survival, use of subsequent anti-cancer therapy, and the long-term safety of subjects. The duration of the study will vary for each subject. Each subject will participate in this study until withdrawal of consent, death, or end of study, whichever occurs first. The registry study will end when the sponsor (in consultation with the regulatory authorities) has determined that the collection of long-term safety and survival data are no longer necessary.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Multiple centres: 52 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.
medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/01/2014

Study start date
Actual: 26/04/2010

Data analysis start date
Planned: 03/12/2021

Actual: 03/11/2021

Date of final study report
Planned: 22/04/2022

Actual: 22/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Amendment talimogene laherparepvec 20120139 3 .pdf

(820.99 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Regulatory procedure number

2015-003196-29

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

Main study objective:

The main objectives of this study are to: evaluate the long-term safety of talimogene laherparepvec, monitor subject overall survival monitor use of subsequent anti-cancer therapy, for the tumor indication in the prior Amgen or BioVEX-sponsored clinical trial, including retreatment with marketed talimogene laherparepvec in subjects previously enrolled in Amgen or BioVEX-sponsored trials.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational registry

Study drug and medical condition

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

TALIMOGENE LAHERPAREPVEC

Anatomical Therapeutic Chemical (ATC) code

(L01XX51) talimogene laherparepvec

talimogene laherparepvec

Population studied

Short description of the study population

Investigators will be expected to maintain a screening log of all potential study candidates, including the date of screening and the outcome of the screening process (eg, enrolled into study, reason for ineligibility). Before any study activities begin, including data collection, the appropriate written informed consent/assent must be obtained.

Inclusion Criteria

- All subjects must provide informed consent prior to initiation of any study activities. When the subject is legally too young to provide informed consent/assent, subject’s legally acceptable representative must provide informed consent/assent based on local regulations and/or guidelines prior to initiation of any study activities
- All subjects must have received at least one dose of talimogene laherparepvec on an Amgen or BioVEX-sponsored clinical trial for any tumor type and must have discontinued treatment and participation, including long-term follow-up (if applicable) in that trial

Exclusion Criteria

- Subjects currently receiving talimogene laherparepvec in Amgen or BioVEX-sponsored clinical trial
- Subject currently participating, including for long-term follow-up (if applicable), in other Amgen-sponsored talimogene laherparepvec clinical trial.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

186

Study design details

Outcomes

• subject incidence of all talimogene laherparepvec treatment-related adverse events (AEs) of any grade, grade ≥ 3 AEs, serious and fatal AEs, and AEs of interest that begin after the defined reporting period has ended on the previous Amgen or BioVEX-sponsored talimogene laherparepvec clinical trial
• survival status
• use of subsequent anti-cancer therapy for specific tumor type.

Data analysis plan

The statistical reporting of the safety endpoints and overall survival will be entirely descriptive, with no formal statistical testing performed. Descriptive analyses and listings for the safety endpoints are planned. Categorical outcomes will be described using the frequency and percent. Continuous outcomes will be described using the mean, median, standard deviation, minimum, and maximum. AEs will be coded with the most recent version of Medical Dictionary for Regulatory Activities and will be grouped by system organ class and preferred term (PT) within system organ class. Event severity will be graded using CTCAE version 4.0.

Documents

Study results

20120139 Clinical Study Report Synopsis.pdf (333.79 KB)

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)

Other

Data sources (types), other

Prospective patient-based data collection

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