Non-Interventional Study To Investigate The Effectiveness, Safety And Utilization Of Vismodegib On Locally Advanced Basal Cell Carcinoma Under Real World Conditions (NIELS)

First published: 13/07/2015

Last updated: 01/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS10089

Study ID

30219

DARWIN EU® study

No

Study countries

Germany

Study description

STUDY TO INVESTIGATE THE EFFECTIVENESS, SAFETY AND UTILIZATION OF VISMODEGIB ON LOCALLY ADVANCED BASAL CELL CARCINOMA UNDER REAL WORLD CONDITIONS

Study status

Finalised

Research institutions and networks

Institutions

NA

Multiple centres: 30 centres are involved in the study

Contact details

Study institution contact

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Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Andrea Kempf-Mueller

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 27/01/2015

Study start date
Planned: 15/09/2015

Actual: 17/09/2015

Date of final study report
Actual: 31/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

ML29670

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The aim of this multi-center, non-interventional study is to provide further data on effectiveness with a special focus on duration of response, safety and utilization of Vismodegib for treatment of laBCC in daily practice in Germany.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Drug interaction study

Study drug and medical condition

Medicinal product name, other

Erivadge

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

VISMODEGIB

Anatomical Therapeutic Chemical (ATC) code

(L01XX43) vismodegib

vismodegib

Additional medical condition(s)

LOCALLY ADVANCED BASAL CELL CARCINOMA

Population studied

Short description of the study population

Locally advanced basal cell carcinoma

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)

Special population of interest

Other

Special population of interest, other

Basel cell carcinoma patients

Estimated number of subjects

100

Study design details

Outcomes

Duration of response defined as duration from first documented response of complete response (CR) or partial response (PR) until disease progression (as determined by the treating physician) for laBCC patients, •Objective response rate (ORR) (CR + PR)•Disease control rate (CR + PR + SD)•Recurrence rate•Progression free survival time and overall survival•Time to response•All protocol-specified adverse events (AEs) •Incidence, risk factors, and outcomes

of serious and non-serious AEs of interest

Data analysis plan

No formal statistical hypothesis and no formal sample size calculation will be performed.All efficacy and safety variables documented in this study will be analyzed by means of descriptive analysis.Continuous data will be summarized using mean, standard deviation, median, minimum and maximum. Categorical variables will be expressed as absolute and relative number and 95% CI. Kaplan-Meier estimates and Cox-regression will be used to model data on time to disease progression and duration of response.

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, Patients' records

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