Risk of squamous cell carcinoma in patients treated for basal cell carcinoma with Vismodegib or other therapies

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Study Finalised

Administrative details

EU PAS number

EUPAS21160

Study ID

24704

DARWIN EU® study

No

Study countries

United States

Study description

Comparison of pooled outcome data from patients treated with vismodegib as part of completed and ongoing phase I and II clinical studies with data from theUniversity of California, San Francisco (UCSF) Nonmelanoma Skin Cancer Cohort study of patients treated for primary basal cell carcinoma with standard therapy.Using these two cohorts, the aim was to determine whether treatment with vismodegib is associated with an increase in the risk of cutaneous SCC.

Study status

Finalised

Research institutions and networks

Institutions

University of California, San Francisco

Contact details

Study institution contact

Clinical Trials Hoffmann-La Roche

global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Jeannie Hou

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 09/12/2013

Study start date
Actual: 01/01/2014

Date of final study report
Actual: 28/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genentech, Inc./Hoffmann-La 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

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:

Secondary use of data

Main study objective:

To determine whether patients with basal cell carcinoma treated with vismodegib have an increased risk of SCC at one year compared to patients treated with other therapies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

VISMODEGIB

Medical condition to be studied

Squamous cell carcinoma

Population studied

Short description of the study population

Patients treated with vismodegib as part of 2 phase II (STEVIE and ERIVANCE) and 2 phase I clinical trials.

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

Squamous cell carcinoma patients

Estimated number of subjects

1.700

Study design details

Outcomes

1) Incidence rates of SCC at one year post initiation of treatment, stratified by key potential risk factors for development of SCC (eg. age, gender, prior NMSC). 2) Standardized incidence rate ratio of SCC at one year post initiation of treatment.3) Relative hazard of SCC in vismodegib treated vs non-exposed patients.

Data analysis plan

Baseline demographic characteristics were assessed for both cohorts at the time of treatment of BCC and were analyzed using descriptive statistics. Means and standard deviations were used for continuous variables, and percentages were used for categorical variables.Standardized incidence ratios were calculated for diagnosis of SCC at 1 year after treatment start (vismodegib treatment and surgery, respectively) using vismodegib treated patients as the exposed group. Relative risks were also calculated for clinical variables of age,gender, ethnicity, and basal cell nevus syndrome. Cox proportional hazards models were used to estimate hazard ratios (HR) and their 95% confidence intervals (CI) to assess the association between treatment with vismodegib and the development of SCC.

Documents

Study results

Risk of cutaneous squamous cell carcinoma after treatment of basal cell carcinoma with vismodegib.pdf (153.48 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

Four Vismodegib clinical trials, and one prospective cohort study on standard therapy

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