MELANIS - Survival in adult patients with BRAF V600 mutation-positive advanced melanoma: a non-interventional ambispective study of a cohort of patients treated with cobimetinib during the French early access program (TAU)

Head :Roche Medical data center

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General

Identification

Detailed name	Survival in adult patients with BRAF V600 mutation-positive advanced melanoma: a non-interventional ambispective study of a cohort of patients treated with cobimetinib during the French early access program (TAU)
Sign or acronym	MELANIS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML29964

General Aspects

Medical area	Cancer research Dermatology, venereology
Study in connection with Covid-19	No
Pathology (details)	Onco dermatology, BRAF V600 melanoma
Health determinants	Medicine
Keywords	cobimetinib

Scientific investigator(s) (Contact)

Name of the director	Roche Medical data center
Address	4 cours de l'Ile Seguin - 92100 Boulogne-Billancourt
Email	data_sharing.france@roche.com
Organization	Roche SAS

Collaborations	
Participation in projects, networks and consortia	No
Funding	
Funding status	Private
Governance of the database	
Sponsor(s) or organisation(s) responsible	Roche SAS
Organisation status	Private
Presence of scientific or steering committees	Yes
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	Primary Objective: To estimate the OS of patients treated with cobimetinib in combination with vemurafenib Secondary Objectives: - To assess the PFS - To identify prognostic factors of OS - To identify prognostic factors of PFS - To describe response to treatment (overall assessment of the physician) - To describe time to treatment discontinuation. - To characterize the targeted AE of cobimetinib in combination with vemurafenib under real-world

	conditions of useTo describe the long term safety profile of cobimetinib in association with vemurafenib under real-world conditions of use Exploratory Objectives: - To describe population of patients treated with cobimetinib in combination with vemurafenib - To describe the use of cobimetinib in combination with vemurafenib
Inclusion criteria	Inclusion criteria: - Patients at least 18 years-old - Patients included in the TAU from 26 February 2015 - Patients with BRAF V600 mutation-positive unresectable or metastatic melanoma treated with cobimetinib in combination with Zelboraf® (vemurafenib) - For alive patients: patients who have been informed verbally and in writing about this study who do not object to their data being electronically processed or subjected to data quality control and who have signed the consent form OR - For patients who died before the inclusion period: patients who did not expressed their opposition when they were alive. Exclusion criteria: - Alive patients unable to give informed consent - Patients previously included in cobimetinib clinical trial.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Pathology	C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue
Gender	Male Woman
Geography area	National
Data collection	
Dates	

Date of first collection (YYYY or MM/YYYY)	2016
Date of last collection (YYYY or MM/YYYY)	2018
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	198
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Medical registration
Details of collected clinical data	Type of data collected : informed consent, inclusion/exclusion criteria, date of the visit, demographic data, clinical data, medical history, disease history and prior melanoma therapies, treatment with cobimetinib, concomitant medications for melanoma (including vemurafenib), first disease progression, evaluation of lesions (as assessed by the physician), vital status, targeted adverse events (before inclusion), adverse events (after inclusion), early study termination.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Procedures	
Data collection method	eCRF
Classifications used	CDISC like
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor

Followed pathology	C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue
Links to administrative sources	No

Promotion and access

Promotion

Access

Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only