A Global Enhanced Pharmacovigilance Pregnancy Surveillance Study of Pregnant Women Exposed to Yervoy® with 5-year Pediatric Follow-up (CA184-487)

First published: 19/05/2017

Last updated: 23/03/2021

Study Finalised

Administrative details

EU PAS number

EUPAS18596

Study ID

40257

DARWIN EU® study

No

Study countries

- ☐ Brazil
- ☐ Canada
- ☐ France

- [ ] Germany
- [ ] Italy
- [ ] Poland
- [ ] United Kingdom
- [ ] United States

Study description

Although cancer during pregnancy is not common, melanoma is among the most common cancers observed in pregnant women. The incidence of melanoma among pregnant women is expected to continue to increase, as it has done in recent decades. Evidence suggests that pregnant women with melanoma have no worse a prognosis than non-pregnant women with melanoma, and that maternal and birth outcomes may be quite good depending upon the stage of disease. The data on Yervoy® (ipilimumab) exposure and human pregnancy available to date are very limited as pregnant women are excluded from clinical trials. The effects of exposure to ipilimumab during pregnancy on development of the fetal immune system and other organs that are susceptible to immune-mediated adverse reactions are unknown. The purpose of this study is to monitor pregnancies exposed to ipilimumab to evaluate the possible adverse effects of this immunotherapy on the pregnancy outcome and on delays in growth and development milestones, clinical signs of immune or endocrine dysfunction, autoimmune disorders, reactions to immunizations/vaccinations, hospitalizations for serious infection and malignancies in the first 5 years of life. The lack of human fetal safety data for ipilimumab makes such a monitoring system an important component of epidemiologic research on the safety of this drug when treating melanoma during pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

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Institution

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Xianying Pan

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2017

Actual: 25/02/2016

Study start date
Planned: 30/09/2016

Actual: 26/09/2016

Date of final study report
Planned: 20/10/2020

Actual: 05/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

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 type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The research question to be addressed by this safety surveillance study is: what are the pregnancy outcomes and offspring outcomes through 5 years of life following maternal exposure to ipilimumab during pregnancy or 90 days within treatment discontinuation?Study population: 1) pregnant women, 2) new-born, infants and children (male and female) up to 5 years of age.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Safety surveilance study

Study drug and medical condition

Name of medicine

YERVOY

Medical condition to be studied

Malignant melanoma

Population studied

Short description of the study population

Pregnant women exposed to ipilimumab.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

10

Study design details

Outcomes

Pregnancy: Pregnancies resulting in spontaneous or elective abortion, fetal death, preterm birth, ectopic or molar pregnancyFetal and pediatric: Small-for gestational age, birth defects, congenital anomalies, delays in growth and development milestones, clinical signs of immune or endocrine dysfunction, autoimmune disorders, reactions to vaccinations, hospitalizations, and malignancy

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Data analysis plan

A formal statistical analysis plan (SAP) will include details of all planned analyses and presentation of study data. Since this is an observational study, descriptive analyses will be provided. Descriptive statistics will comprise the number of observations (n), mean, standard deviation (SD), median, minimum, and maximum for continuous variables, and n and percent for categorical variables. Data will be presented for all patients enrolled in the study. An analysis of all study participants combined will be provided. Separate analyses will also be conducted for prospective and retrospective reports.

Data management

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