# 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





### 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)

First published: 01/02/2024

**Last updated:** 01/02/2024

Institution

Multiple centres: 50 centres are involved in the

study

### Contact details

### **Study institution contact**

Xianying Pan xianying.pan@bms.com

Study contact

xianying.pan@bms.com

### **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

#### 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

### **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 (type: Other	)
<b>Data sources (type</b> Prospective patient-b	
Use of a Com	mon Data Model (CDM)
<b>CDM mapping</b> No	
Data quality s	pecifications
Check conformance	
Unknown	
Check completenes	5
Unknown	
Check stability	

# Data characterisation

### **Data characterisation conducted**

No