

# 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)

**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](mailto:xianying.pan@bms.com)

Study contact

[xianying.pan@bms.com](mailto: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 surveillance study

## Study drug and medical condition

**Medicinal product name**

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 pregnancy  
Fetal 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 (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