Postmarketing commitment safety study of HZ/su to evaluate pregnancy exposures and outcomes in immunodeficient or immunosuppressed women between 18 and 49 years of age (EPI-ZOSTER-039 VS US DB 214420)

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### Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/105603

#### **EU PAS number**

EUPAS104070

### **Study ID**

105603

#### **DARWIN EU® study**

No

### **Study countries**

United States

### **Study description**

The study will examine the risk of selected infant and pregnancy outcomes in immunodeficient or immunosuppressed women exposed to herpes zoster subunit vaccine (HZ/su) during pregnancy.

### **Study status**

Ongoing

### Research institutions and networks

### **Institutions**

### GlaxoSmithKline (GSK)

First published: 01/02/2024

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

Institution

### Harvard Pilgrim Health Care Institute

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### Contact details

### **Study institution contact**

Call Center EU GSK Clinical Trials

Study contact

RD.CTT-globalmailbox@gsk.com

### **Primary lead investigator**

Call Center EU GSK Clinical Trials

**Primary lead investigator** 

## Study timelines

### Date when funding contract was signed

Actual: 09/11/2022

#### Study start date

Planned: 03/04/2023

Actual: 09/05/2022

### **Date of final study report**

Planned: 30/04/2029

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

**GSK** 

## Study protocol

Protocol\_Amendment\_2\_Anonymized.pdf(1.03 MB)

## 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 type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

### Main study objective:

To evaluate the prevalence of major congenital malformations (MCMs) among live births from women with immunocompromised (IC) conditions exposed to HZ/su compared to those not exposed to HZ/su during pregnancy.

## Study Design

### Non-interventional study design

Cohort

## Study drug and medical condition

#### Name of medicine

**SHINGRIX** 

#### Medical condition to be studied

Herpes zoster

# Population studied

### Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

### **Special population of interest**

Immunocompromised

#### **Estimated number of subjects**

2844

## Study design details

#### **Outcomes**

Major congenital malformations (MCMs) among live births from women with immunocompromised (IC) conditions exposed to HZ/su compared to those not exposed to HZ/su during pregnancy.

Additional infant/birth outcomes among live births in women with IC conditions exposed to HZ/su versus those not exposed to HZ/su during pregnancy.

Pregnancy outcomes and pregnancy complications among livebirth and non-livebirth pregnancies in women with IC conditions exposed to HZ/su versus those not exposed to HZ/su during pregnancy.

#### Data analysis plan

Annual descriptive analyses to estimate the counts of HZ/su exposed pregnancies among women with IC conditions will be performed.

Data from the first two years will be used to determine the feasibility of a fullscale cohort study.

If the feasibility assessment identifies that the number of HZ/su-exposed pregnancies is equal to or above the target number of exposed pregnancies, a subsequent cohort study will be conducted.

The prevalence of MCMs and additional infant/birth outcomes and their associated 95% CIs will be calculated among women with IC conditions who were exposed to HZ/su during pregnancy versus the corresponding matched women who were not exposed to HZ/su during pregnancy.

The prevalence of the pregnancy outcomes and pregnancy complications and

their 95% CIs will be calculated between the two groups of women.

All analyses will be stratified by stage of pregnancy (pre-pregnancy, first trimester, second trimester, third trimester).

### Data management

### Data sources

### Data source(s), other

CVS Health Clinical Trial Services United States, HealthCore, Inc United States, Optum United States

### Data sources (types)

Administrative healthcare records (e.g., claims)

### 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