

# An open label, multi-centre, post marketing surveillance (PMS) to monitor the safety and efficacy of INCRUSE administered in Korean subjects with chronic obstructive pulmonary disease (COPD) in usual practice (205163)

**First published:** 30/08/2016

**Last updated:** 23/05/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/40153>

### EU PAS number

EUPAS14947

### Study ID

40153

### DARWIN EU® study

No

### Study countries

Korea, Republic of

### Study description

An open label, multi-centre, post marketing surveillance (PMS) to monitor the safety and effectiveness of Incruse administered in Korean subjects with chronic obstructive pulmonary disease (COPD) in usual practice

### Study status

Finalised

## Research institution and networks

## Institutions

### GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated 01/02/2024

Institution

Je-Ju National University Hospital Je-Ju, Korea

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned:

13/10/2015

Actual:

13/10/2015

---

### Study start date

Planned:

31/08/2016

Actual:

23/08/2016

---

### Date of final study report

Planned:

09/10/2020

Actual:  
03/09/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[gsk-205163-protocol-redact.pdf](#)(402.67 KB)

## 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

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness  
Effectiveness study (incl. comparative)  
Safety study (incl. comparative)

**Data collection methods:**

Combined primary and secondary data collection

---

**Main study objective:**

To collect safety and effectiveness data of Incruse in Korean COPD patients.

## Study Design

**Non-interventional study design**

Cohort  
Other

---

**Non-interventional study design, other**

Open-label, single arm, multi-centre post marketing surveillance (PMS). No comparator cohort will be included in this study

## Study drug and medical condition

**Name of medicine**

Incruse

---

**Study drug International non-proprietary name (INN) or common name**

UMECLIDINIUM BROMIDE

## Population studied

**Short description of the study population**

Korean subjects with chronic obstructive pulmonary disease (COPD) in usual practice.

**Inclusion criteria**

All subjects must satisfy the following criteria

- Adult subjects (19 years and older) who have chronic obstructive pulmonary disease (COPD) -Pulmonary Function Test: Post bronchodilator, FEV1/FVC < 0.7
- Subjects who will administer INCRUSE according to locally approved prescribing information

**Exclusion criteria**

- Subject who has medical history of hypersensitivity to the active substances or main substances or atropine derivative(i.e. ipratropium,tiotropium, oxitropium, glycopyrronium, aclidinium)
  - Subject with severe hypersensitivity to milk proteins
  - Subject with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucosegalactose malabsorption
- 

### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

---

### **Special population of interest**

Hepatic impaired

Pregnant women

Renal impaired

---

### **Estimated number of subjects**

600

---

## **Study design details**

### **Outcomes**

Primary objective is to monitor adverse events, including unexpected adverse events and/or serious adverse events, reported after administering at least 1 dose of Incruse.-

Minimum of one follow-up visit after administration of Incruse in order to assess safety,

Secondary objective is to monitor effectiveness after administering Incruse, as determined by post BD FEV1 on Treatment Week 24.- Minimum 24 weeks follow-up after administering Incruse for effectiveness

---

### **Data analysis plan**

Safety analyses will be based on the population, defined as subjects who receive at least one dose of the Incruse and completed at least one safety assessment. In general, data summaries will be presented overall and by the subgroups of interest. Baseline characteristics will be summarized using descriptive statistics. The number and percentage of subjects reporting adverse event after administration of Incruse will be tabulated. Cases with serious adverse events and/or unexpected adverse drug reactions will be described in detail. The distribution of adverse events will be tabulated. The percentage of subjects reporting adverse events will be analyzed using Chi-square test or Fisher's exact test stratified by potential confounding factors for subgroup analysis. The percentage of subjects reporting adverse events among specific population e.g. the elderly will be tabulated respectively. The difference of the incidence of adverse events by each factor will be analyzed.

---

## **Documents**

## Study results

[gsk-205163-clinical-study-report-redact.pdf](#) (5.41 MB)

---

## Data management

### Data sources

#### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

[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