Post Marketing Active Surveillance to Evaluate the Safety and Efficacy of Aprepitant (EMEND®) for the Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV) Associated with High Emetogenic Cancer Chemotherapy in China (MK-0869-804)

First published: 11/07/2019 Last updated: 27/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS29952

Study ID

29953

DARWIN EU® study

No

Study countries

China

Study description

This was a multi-center, prospective, non-interventional surveillance study to assess the safety and efficacy of aprepitant in the prevention of chemotherapyinduced nausea and vomiting (CINV) in Chinese participants with solid malignancies who were treated with a highly emetogenic chemotherapy (HEC) regimen. Participants received 125 mg of oral aprepitant one hour prior to HEC chemotherapy on Day 1 and 80 mg of oral aprepitant once daily on the mornings of Days 2 and 3. Participants who took at least one dose of aprepitant were surveyed using diaries that included the following: the Multinational Association of Supportive Care in Cancer (MASCC) Antiemesis Tool (MAT), Functional Living Index-Emesis (FLIE) questionnaire, and a medication questionnaire. In addition, participants were contacted by investigators to assess adverse event (AE) up to 14 days after the last dose of aprepitant.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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The First Affiliated Hospital of Medical School of Zhejiang University Hangzhou, Zhejiang Province, People's Republic of China

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed Actual: 30/01/2014

Study start date

Actual: 15/07/2014

Data analysis start date

Actual: 25/04/2016

Date of final study report Actual: 20/10/2017

Sources of funding

• Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

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:

Disease /health condition 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:

Primary data collection

Main study objective:

This was a non-interventional surveillance study to assess the safety and efficacy of aprepitant in the prevention of chemotherapy-induced nausea and vomiting (CINV) in Chinese participants with solid malignancies who were treated with a highly emetogenic chemotherapy (HEC) regimen.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Single-arm, prospective, post-marketing surveillance study

Study drug and medical condition

Name of medicine

EMEND

Anatomical Therapeutic Chemical (ATC) code

(A04AD12) aprepitant aprepitant

Medical condition to be studied

Nausea Vomiting

Population studied

Short description of the study population

Chinese patients, 18 years of age or above, both males and females, with a solid malignancy, who are treated with HEC regimens. To participate in this surveillance, patients are those who received at least one dose of Aprepitant, prior to HEC regimen.

Inclusion Criteria

All inclusion and exclusion criteria will be reviewed by the investigator or qualified designee to ensure the patient is qualified for the survey.

- 1. Adult male or female, 18 years Of age Or Older.
- 2. Patient must be willing to give written infonned consent.
- 3. Patient is scheduled to receive his/her highly emetogenie chemotherapy.
- 4. Patient who is treated with Aprepitant for the first time.
- 5. Patient is able to read, understand and complete the patient diaries.

Exclusion Criteria

 Patient having any medical condition or concurrent use Of medications, which may be contraindication to the approved local prescribing information as per the investigator's opinion. Contraindication to Aprepitant.

The patient who has one or more of the following conditions:

i) Aprepitant is a moderate cytoehrome P450 isoenzyme 3A4 (CYP3A4) inhibitor. Aprepitant should not be used concurrently with pimozide, terfenadine, astemizole, or eisapride. Inhibition Of CYP3A4 by Aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions.

ii) Aprepitant is contraindicated in patients who are hypersensitive to any component of the product.

2. Patient has received a non-approved (investigational) drug within the last 4 weeks.

3. Any condition which, in the opinion of the investigator may confound the results of the survey or pose unwarranted risk in administering study drug to the patient.

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

Other

Special population of interest, other

Solid malignancy patients

Estimated number of subjects

1000

Study design details

Outcomes

The primary outcome was related to safety and included the proportion of one or more of the following: adverse event(s), drug-related adverse event(s), serious adverse event(s), and discontinuations due to an adverse event(s). The secondary outcome was related to efficacy and included complete response at 0 to 120, 0 to 24, and 25 to 120 hours, no vomiting at 0 to 24, 25 to 120, and 0 to 120 hours, no significant nausea at 0 to 120 hours, no nausea at 0 to 120 hours, and no impact on daily life at 0 to 120 hours.

Data analysis plan

The primary outcomes were summarized by number of events, observed incidence, and corresponding 95% CI (Clopper-Pearson) by descriptive statistics. The primary outcome was further analyzed by: age (<55, >=55 years), gender, and clinical characteristics derived by medical history including chemotherapy regimen(s), cancer diagnosis, clinically significant prior/concomitant medications (including Traditional Chinese Medicines), and the timing of aprepitant administration.The secondary outcomes were summarized by count, point estimate and corresponding 95% confidence interval (Clopper-Pearson), and analyzed by: age (<55, >=55 years), gender, and clinical characteristics derived by medical history including chemotherapy regimen(s), cancer diagnosis, clinically significant prior/concomitant medications (including Traditional Chinese Medicines), and the timing of aprepitant administration.

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, Multinational Association of Supportive Care in Cancer (MASCC) Antiemesis Tool (MAT), Functional Living Index-Emesis (FLIE) questionnaire, and a medication questionnaire

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