TAK-633-4008: Quantitative Testing of Patient and Prescriber Knowledge, Attitudes, and Behavior about GATTEX (Teduglutide) for Injection Safety and Use Information (GATTEX KAB)

First published: 28/09/2022

Last updated: 06/12/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS48716

Study ID

49716

DARWIN EU® study

No

Study countries

☐ United States

Study description

The main aim of this study is to check the level of knowledge and assess attitudes and behaviors of both participants and physicians regarding the risks and safe use of GATTEX. The survey will be done via internet, telephone, or paper and both physicians and participants will be able to choose the method that is preferred.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Takeda medinfoUS@takeda.com

Study contact

medinfoUS@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/08/2013

Study start date
Actual: 01/08/2013

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

NCT05561647 (https://clinicaltrials.gov/ct2/show/NCT05561647),TAK-633-4008 (https://clinicaltrials.takeda.com/study-detail/43674fa3720540ed?idFilter=%5B%22TAK-633-4008%22%5D)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Knowledge, Attitude, Behavior Survey

Main study objective:

The main aim of this study is to document the level of knowledge and assess attitudes and behaviors of both participants and physicians regarding the risks and safe use of GATTEX. The survey will be done via internet, telephone, or

paper and both physicians and participants will be able to choose the method that is preferred.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey

Study drug and medical condition

Name of medicine, other

GATTEX

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

TEDUGLUTIDE

Anatomical Therapeutic Chemical (ATC) code

(A16AX08) teduglutide

teduglutide

Medical condition to be studied

Short-bowel syndrome

Population studied

Short description of the study population

Participants and prescriber who have completed Wave 7 of the GATTEX participant KAB Survey will be observed in this REMS survey.

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)

Estimated number of subjects

600

Study design details

Outcomes

Number of Participants and Prescribers Providing Correct Responses to Questions. Number of Participants and Prescribers Providing Correct Responses (80%) to and Demonstrated Understanding of Survey Knowledge Domains.

Data analysis plan

Detailed statistical analysis methods will be conducted as described in the SAP for this study. Data will be summarized with tabulated descriptive statistics: number of observations, minimum, maximum, mean, median, standard deviation, and range for continuous variables and counts and percentages for categorical variables. In addition, graphical data displays will be used to summarize selected data.

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

Patient surveys

Data sources (types), other

The primary source for this study is the Knowledge, Attitudes and Behavioral (KAB) and Risk Evaluation and Mitigation Strategy (REMS) surveys. Survey will be administered via internet, phone, or paper.

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

Unknown