Real-world clinical outcomes, patient characteristics, and treatment patterns among patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2-negative, claudin-18 isoform 2-positive gastric or gastroesophageal junction adenocarcinoma treated with zolbetuximab or other first line treatments: A cohort study using secondary data in Europe and Canada (RADIANCE)

First published: 01/10/2026

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Study Planned

Administrative details

EU PAS number

EUPAS1000001120

Study ID

1000001120

DARWIN EU® study

No

Study countries

- Canada
- France
- Germany
- Portugal
- Spain
- Sweden

Study description

There is an unmet medical need to treat people with advanced cancer in the stomach, or where the food pipe joins the stomach. These conditions are known as advanced gastric cancer or advanced gastroesophageal cancer (GEJ for short).

Zolbetuximab is an approved treatment for people with advanced stomach (gastric) cancer or advanced GEJ cancer. Some people with stomach or GEJ cancer have a protein called Claudin 18.2 in their tumor. Zolbetuximab works by attaching to the Claudin 18.2 protein in their tumor. This switches on the body’s immune system to attack the tumor.

The main aim of the study is to collect information about zolbetuximab and other cancer treatments in people with advanced gastric or GEJ cancer. This includes safety information, how long people respond to treatment and how long people live for without their cancer getting worse.

This study is about collecting information only. This is known as an observational study. The individual’s doctor decides on treatment, not the sponsor (Astellas).

This study will use information from European and Canadian health registries and databases to learn more about people with advanced gastric or GEJ cancers who used zolbetuximab and other cancer treatments. The entire study will last about 4 years.

Study status

Planned

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Anouk Van Oosten

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 11/12/2024

Study start date
Planned: 31/01/2027

Data analysis start date
Planned: 31/05/2027

Date of interim report, if expected
Planned: 31/08/2028

Date of final study report
Planned: 31/03/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

8951-MA-3584

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a descriptive cohort study of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma in Europe and Canada. This study will use secondary data sources and employ a waved design for retrospective data collection and analysis.

Main study objective:

The main aim of the study is to collect information about zolbetuximab and other cancer treatments in people with advanced gastric or GEJ cancer. This includes safety information, how long people respond to treatment and how long people live for without their cancer getting worse.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VYLOY

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

ZOLBETUXIMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX31) zolbetuximab

zolbetuximab

Medical condition to be studied

Gastric cancer

Population studied

Short description of the study population

There is an unmet medical need to treat people with advanced cancer in the stomach, or where the food pipe joins the stomach. These conditions are known as advanced gastric cancer or advanced gastroesophageal cancer (GEJ for short). Some people with stomach or GEJ cancer have a protein called Claudin 18.2 in their tumor.

Age groups

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

Estimated number of subjects

1.000

Study design details

Outcomes

1. Overall survival (OS)
2. Real-world progression free survival (rwPFS)
3. Time to next treatment (TTNT)
4. Time to next treatment or death (TTNTD)
5. Real-world time to progression (rwTTP)
6. Real-world duration of response (rwDOR)
7. Real-world response rate (rwRR)
8. Real-world disease control rate (rwDCR)
9. Real-world tumor growth rate (rwTGR)
10. AEs
11. Duration of AEs
12. Time to first AE
13. Serious AEs (SAEs)
14. Duration of SAEs
15. Time to first SAE
16. Inpatient hospitalizations
17. Management of nausea/vomiting

Data analysis plan

Time-to-event variables will be analyzed using Kaplan-Meier method if death is one of the events of interest. Otherwise, death will be considered a competing event, and a non-parametric estimator of the cumulative incidence function will be used. All time-to-event endpoints will be depicted graphically using cumulative incidence functions to enable an easier comparison, with the number of patients still at risk at discrete time points tabulated below the curves. Median survival time will be reported for each outcome, along with the IQR and 2-sided 95% CIs. The probability of experiencing the event(s) of interest by each time point will be estimated and reported along with the corresponding 2-sided 95% CIs.

Descriptive statistics will be used to report all other variables, as applicable. Continuous variables will be described by the mean, standard deviation (SD), median, IQR and minimum and maximum values (where possible). Categorical variables will be described by the number and percentage of patients in each category. The number of patients with missing data for each variable will be reported; no imputation for missing data will be performed.

Data will be pooled across all data sources that are able to share individual patient data. Additionally, to obtain pooled estimates of all clinical outcomes across all countries and data sources, meta-analysis will be performed for Cohorts A and B. Country-specific estimates for each clinical outcome will be aggregated using a random effects model with inverse variance weighting using the DerSimonian and Laird approach. Cohorts are expected to be comparable due to the consistent study design across countries; however, statistical heterogeneity will be assessed using the I^2-statistic, with values >50% interpreted as indicative of substantial heterogeneity.

Analyses will be descriptive in nature, with no statistical tests or formal comparisons between cohorts performed unless otherwise noted.

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 source(s), other

Oncology Outcomes

SAPHIR

AGAMENON

The Swedish National Register for Esophageal and Gastric Cancer

Electronic Medical Record-enabled sites

Data sources (types)

Administrative healthcare records (e.g., claims)

Cancer registry

Electronic healthcare records (EHR)

Pharmacy dispensing records

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