An International, Non-Interventional, Post-Authorization Long-Term Safety Study of Lutathera®, in Patients with Unresectable or Metastatic, Well-Differentiated, Somatostatin Receptor Positive, Gastroenteropancreatic Neuroendocrine Tumours (SALUS Study)

First published: 03/10/2018

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS25735

Study ID

49428

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

This is a multinational, multicentre, non-interventional, retrospective and prospective study of patients with GEP-NET receiving treatment with Lutathera. This post-authorization safety study will be conducted with the aim to assess the safety profile of Lutathera and to characterize further the potential safety hazards described in the Risk Management Plan (RMP). It is part of the MAH-proposed safety management to monitor the long-term safety follow-up of Lutathera in the post-authorization setting. The SALUS study will be implemented with the objective to address the important identified risks, important potential risks, and relevant missing information from the controlled clinical trials conducted to obtain the marketing authorization of Lutathera.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Office

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/12/2017

Study start date

Actual: 28/11/2018

Data analysis start date

Planned: 30/06/2028

Date of final study report

Planned: 30/11/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Advanced Accelerator Applications, a Novartis Company

Study protocol

SALUS PROTOCOL_v 1.1 FINAL 15 June 2018_clean_Redacted (1).pdf(848.71 KB)

SALUS PROTOCOL_v 2.2 clean_final_signed with bookmark_Redacted.pdf(863.44 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

A-LUT-T-E02-402,CAAA601A12402,NCT03691064

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Safety study (incl. comparative)

Main study objective:

To assess the incidence and nature of potential long term second primary malignancies, including solid tumours and haematological neoplasia, in patients with unresectable or metastatic, well-differentiated, somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Drug interaction study, Long term safety study

Study drug and medical condition

Name of medicine

LUTATHERA

Additional medical condition(s)

Unresectable or Metastatic, Well-Differentiated, Somatostatin Receptor Positive, Gastroenteropancreatic Neuroendocrine Tumours

Population studied

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

1000

Study design details

Outcomes

Incidence and type of a second primary cancer (a solid tumour or an haematological cancer). a. AEs and SAEs related to Lutathera b. AEs/SAEs of special interest related to Lutathera as outlined in the RMP. c. mortality (all causes) d. new AEs/SAEs related to Lutathera, in particular those related to the safety concerns classified as “missing information” in the RMP e. Impact of tumour location at baseline on the safety profile. f. Description of Lutathera use patterns

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Data analysis plan

The primary analysis population will be the population of all eligible patients included in the study. The Full Analysis Set will consist of all evaluable subjects

who have received any part of a Lutathera treatment. Patients who consented for the SALUS study are intended to be followed up to 7 years from the start of the study, regardless of incidence of second malignancy, unless they die or they are lost-to-follow-up. Stratified or subgroup analysis might be considered if deemed relevant. All analyses will be performed for all countries and sites together. Categorical variables will be described by counts n and % on each category. Continuous variables will be described by mean, standard deviation, median, interquartile and min-max ranges. No imputation will be performed on missing data. Instead, missing data can be reported as an independent category.

Documents

Study, other information

Centers involved in study EUPAS25735.pdf(19.28 KB)

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

Available data from the NETTER-1 study (Lutathera arm) Available data from the NETTER-2 study Patients enrolled in the CUP/EAP at the selected sites Newly treated patients with Lutathera upon its availability on the market

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