# 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

**PURI**
https://redirect.ema.europa.eu/resource/49428

**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 institution 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
Study contact

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**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

**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

## 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