# Multicenter 3-arm trial to evaluate the efficacy and safety of Pasireotide LAR or Everolimus alone or in combination in patients with well differentiated neuroendocrine carcinoma of the lung and thymus -LUNA Trial

Published: 11-07-2013
Last updated: 24-04-2024

To evaluate the efficacy of pasireotide LAR and everolimus alone or in combination in progressive patients with a well differentiated neuroendocrine tumor of the lung or thymus.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Neoplastic and ectopic endocrinopathies |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON40411

**Source**
ToetsingOnline

**Brief title**
LUNA Trial

### Condition

- Neoplastic and ectopic endocrinopathies
- Endocrine neoplasms malignant and unspecified
- Respiratory tract neoplasms

**Synonym**
Lung carcinoid, Neuroendocrine tumor of the thymus

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Novartis
**Source(s) of monetary or material Support:** Novartis Pharma B.V.

## Intervention

**Keyword:** Everolimus, Lung NET, Pasireotide LAR, Thymus NET

## Outcome measures

### Primary outcome

The primary endpoint is defined as the proportion of patients progression-free

at 9 months according to RECIST 1.1.

### Secondary outcome

* Overall progression-free survival

* Time to response, duration of response and time to progression, objective

response rate and best response

* Biochemical response rate, duration of biochemical response and biochemical

progression free survival

* Rate and severity of AEs

# Study description

### Background summary

This study is based on both preclinical and clinical considerations:
* Combined inhibition of the IGF-1-, the PI3K- and the mTOR-pathways by pasireotide and everolimus may control tumor growth more effectively than either compound alone.
* Combination of everolimus with sandostatin LAR seems to improve progression free survival in NET patients. Thus the combination of everolimus with

pasireotide LAR might result in even better tumor control.

The purpose of this study is to assess efficacy and safety of pasireotide LAR and everolimus alone or in combination.

### Study objective

To evaluate the efficacy of pasireotide LAR and everolimus alone or in combination in progressive patients with a well differentiated neuroendocrine tumor of the lung or thymus.

### Study design

A prospective, multicenter, randomized, open-label, 3-arm, phase II study with a single-stage design in each arm to evaluate the efficacy and safety of pasireotide LAR (SOM230) and everolimus (RAD001) alone or in combination in the treatment of patients with a well differentiated neuroendocrine carcinoma of lung or thymus.

### Intervention

Arm 1 treatment with pasireotide (SOM230) LAR (60 mg/month i.m.),
Arm 2 treatment with everolimus (RAD001) (10 mg/day p.o.),
Arm 3 treatment with pasireotide LAR (60 mg/month i.m.) and everolimus (10 mg/day p.o.)

### Study burden and risks

* Possible toxicity of treatment by pasireotide LAR and everolimus, alone or in combination. Side effects are specified in appendix D of the patient information.
* The study assessments are common medical assessments: blood sampling, echocardiogram (using ultrasound) or MUGA scan (using radiation), CT-scan (using radiation) or MRI. An overview of all study procedures can be found in appendix B of the patient information.
* Frequent study visits

It is not certain that the patient will benefit from the study participation. However, obtained insights might be useful in the future. The extent of the burden to the patient are as to be expected from a phase II study.

## Contacts

### Public

Novartis Pharma B.V.

Raapopseweg 1
Arnhem 6824 DP
NL
**Scientific**
Novartis Pharma B.V.

Raapopseweg 1
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NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

* Histological confirmed advanced well differentiated carcinoma of the lung and thymus;* Patients of all treatment lines can be included;* At least one measurable lesion of disease on CT scan or MRI;* Radiological documentation of disease progression within 12 months prior to randomization;* Adequate liver, renal and bone marrow function;* WHO performancestatus 0-2;Other protocol-defined inclusion criteria may apply

## Exclusion criteria

* Poorly differentiated neuroendocrine carcinoma;* Non-neuroendocrine thymoma;* Patients with severe functional disease requiring symptomatic treatment with somatostatin analogs;* Prior therapy with mTOR inhibitors;* History of liver disease;* Baseline QTcF> 470 msec;* Uncontrolled diabetes mellitus despite adequate therapy;Other protocol-defined exclusion criteria may apply

# Study design

## Design

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|---|---|
| Study phase: | 2 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-11-2013 |
| Enrollment: | 8 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | Afinitor |
| Generic name: | Everolimus |
| Registration: | Yes - NL outside intended use |
| Product type: | Medicine |
| Brand name: | Nog niet bekend |
| Generic name: | Pasireotide LAR |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 11-07-2013 |
| Application type: | First submission |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |

| | |
|---|---|
| Approved WMO Date: | 24-07-2013 |
| Application type: | First submission |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 18-10-2013 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 23-10-2013 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 22-07-2014 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 01-09-2014 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 19-12-2014 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 27-01-2015 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 10-03-2015 |
| Application type: | Amendment |

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|---|---|
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 26-03-2015 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 30-09-2015 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 02-10-2015 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 13-07-2017 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |
| Approved WMO Date: | 14-09-2017 |
| Application type: | Amendment |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2011-002872-17-NL |
| ClinicalTrials.gov | NCT01563354 |
| CCMO | NL44585.031.13 |