Efficacy of Everolimus Alone or in Combination With Pasireotide LAR in Advanced PNET (COOPERATE-1)

Purpose

This study will estimate the treatment effect of everolimus in combination with pasireotide LAR relative to everolimus alone on progression-free survival (PFS) in patients with advanced progressive PNET.

Condition | Intervention | Phase
--- | --- | ---
Islet Cell Tumor | Drug: Everolimus
Drug: Pasireotide + Everolimus | Phase 2

Study Type: Interventional
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Randomized, Open-label Phase II Multicenter Study Evaluating the Efficacy of Oral Everolimus Alone or in Combination With Pasireotide LAR i.m. in Advanced Progressive Pancreatic Neuroendocrine Tumors (PNET) - The COOPERATE-2 Study

Resource links provided by NLM:

Genetics Home Reference related topics: Ewing sarcoma

MedlinePlus related topics: Cancer

Drug Information available for: Sirolimus, Everolimus, Temsirolimus, Pasireotide

U.S. FDA Resources

Further study details as provided by Novartis:

Primary Outcome Measures:

- Treatment effect on progression-free survival (PFS) per RECIST 1.0 [ Time Frame: Once 80 PFS events have occurred ]
  [ Designated as safety issue: No ]
  PFS(progression-free survival) RECIST(Response Evaluation Criteria in Solid Tumors) 80 PFS events are expected after approximately 24 months

Secondary Outcome Measures:

- Safety and tolerability profile of Everolimus alone or in combination with Pasireotide LAR [ Time Frame: Once 80 PFS events have occurred ]
  [ Designated as safety issue: Yes ]
  80 PFS events are expected after approximately 24 months.

- Objective Response Rate (ORR) and Disease Control Rate (DCR) [ Time Frame: Once 80 PFS events have occurred ]
  [ Designated as safety issue: No ]
80 PFS are expected after approximately 24 months.

- Duration of response (DoR) [Time Frame: Once 80 PFS events have occurred] [Designated as safety issue: No]
- 80 PFS are expected after approximately 24 months.

80 PFS events expected after approximately 24 months.

Overall Survival (OS) [Time Frame: Once 80 PFS events have occurred] [Designated as safety issue: No]
- 80 PFS events expected after approximately 24 months.

- The treatment effect on PFS and to assess the predictive probability of success in a possible subsequent phase III study once 105 PFS events have been observed [Time Frame: Once 105 PFS events have occurred] [Designated as safety issue: No]
- 105 PFS events expected after approximately 36 months.

**Enrollment:** 199  
**Study Start Date:** June 2011  
**Estimated Study Completion Date:** March 2015  
**Estimated Primary Completion Date:** June 2013 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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| Experimental: Pasireotide LAR + Everolimus  
Pasireotide LAR (SOM230 LAR)+ Everolimus (RAD001) | Drug: Pasireotide + Everolimus  
Pasireotide LAR 60 mg q28d i.m. (once every 28 days intramuscularly) and everolimus 10mg. qd p.o. (by mouth, daily)  
Other Name: SOM230 LAR + RAD001 |
| Experimental: Everolimus | Drug: Everolimus  
Everolimus 10 mg,qd p.o. (by mouth, daily)  
Other Name: RAD001 |

**Eligibility**

| Ages Eligible for Study: | 18 Years and older |
| Genders Eligible for Study: | Both |
| Accepts Healthy Volunteers: | No |

**Criteria**

**Inclusion Criteria:**
- Advanced histologically confirmed well differentiated pancreatic neuroendocrine tumor
- Progressive disease within the last 12 months
- Measurable disease per RECIST Version 1.0 determined by multiphase MRI or triphasic CT

**Exclusion Criteria:**
- Patients currently requiring somatostatin analog treatment
- Prior therapy with mTOR inhibitors or pasireotide
- Patients with more than 2 prior systemic treatment regimens
- Previous cytotoxic chemotherapy, targeted therapy, somatostatin analogs, or biotherapy within the last 4 weeks

Other protocol-defined inclusion/exclusion criteria may apply

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT01374451

**More Information**

No publications provided

**Responsible Party:** Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier: NCT01374451  
Other Study ID Numbers: CSOM230I2201, 2010-023183-40  
Study First Received: June 14, 2011  
Last Updated: March 7, 2013  
Health Authority: United States: Food and Drug Administration  
Australia: Department of Health and Ageing Therapeutic Goods Administration  
Belgium: Federal Agency for Medicines and Health Products, FAMHP  
Brazil: National Health Surveillance Agency  
Canada: Health Canada  
Denmark: Danish Medicines Agency  
France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)  
Germany: Federal Institute for Drugs and Medical Devices  
Hungary: National Institute of Pharmacy  
Italy: National Institute of Health  
Japan: Pharmaceuticals and Medical Devices Agency  
Netherlands: Ministry of Health, Welfare and Sport  
New Zealand: Medsafe  
Spain: Spanish Agency of Medicines

Keywords provided by Novartis:
- Pancreatic
- Neuroendocrine tumors
- PNET

Additional relevant MeSH terms:
- Neuroendocrine Tumors
- Adenoma, Islet Cell
- Neuroectodermal Tumors
- Neoplasms, Germ Cell and Embryonal
- Neoplasms by Histologic Type
- Neoplasms, Nerve Tissue
- Adenoma
- Neoplasms, Glandular and Epithelial
- Pancreatic Neoplasms
- Digestive System Neoplasms
- Neoplasms by Site
- Endocrine Gland Neoplasms
- Digestive System Diseases

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http://clinicaltrials.gov/ct2/show/NCT01374451?term=CSOM230I220...