Efficacy and Safety Study in Pancreatic or Midgut Neuroendocrine Tumours Having Progressed Radiologically While Previously Treated With Lanreotide Autogel® 120 mg (CLARINET FORTE)

This study is currently recruiting participants. (see Contacts and Locations)

Verified October 2016 by Ipsen

Sponsor:
Ipsen

Information provided by (Responsible Party):
Ipsen

ClinicalTrials.gov Identifier:
NCT02651987

First received: December 11, 2015
Last updated: October 24, 2016
Last verified: October 2016
History of Changes

Purpose

This study aims to explore the efficacy and safety of lanreotide Autogel® 120 mg administered every 14 days in subjects with grade 1 or 2, metastatic or locally advanced, unresectable pancreatic or intestinal neuroendocrine tumours (NETs) once they have progressed on the standard dose of lanreotide Autogel® 120 mg every 28 days.

Condition	Intervention	Phase
Pancreatic Tumours Midgut Neuroendocrine Tumours	Drug: Lanreotide autogel 120 mg	Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Efficacy and Safety of Lanreotide Autogel® 120 mg Administered Every 14 Days in Well Differentiated, Metastatic or Locally Advanced, Unresectable Pancreatic or Midgut Neuroendocrine Tumours Having Progressed Radiologically While Previously Treated With Lanreotide Autogel® 120 mg Administered Every 28 Days

Resource links provided by NLM:

MedlinePlus related topics: Cancer Carcinoid Tumors

Drug Information available for: Lanreotide Lanreotide acetate

Genetic and Rare Diseases Information Center resources: Carcinoid Tumor Neuroepithelioma

U.S. FDA Resources

Further study details as provided by Ipsen:

Primary Outcome Measures:

- Median Progression Free Survival (PFS) Time [Time Frame: Every 14 days up to approximately 102 weeks] [Designated as safety issue: No]

  PFS is defined as time from first injection of lanreotide Autogel® 120 mg every 14 days to progression or death based on Response Evaluation Criteria in Solid Tumours (RECIST) v1.0

Secondary Outcome Measures:

- Median Time to Progression [Time Frame: Every 14 days up to approximately 102 weeks] [Designated as safety issue: No]

  Time to Progression is defined as time from first injection of lanreotide Autogel® 120 mg every 14 days to progression

- Proportion of subjects alive and without progression [Time Frame: Every 12 weeks up to approximately 102 weeks] [Designated as safety issue: No]

Proportion of subjects alive and without progression every 12 weeks

- Overall survival [Time Frame: Week 48 and at end of the study (up to approximately 102 weeks)] [Designated as safety issue: No]

  Overall survival defined as the time from first study treatment to death due to any cause

- Overall Response Rate (ORR) [Time Frame: Every 12 weeks up to approximately 102 weeks] [Designated as safety issue: No]

  ORR every 12 weeks as per RECIST v1.0. is defined as the proportion of subjects who achieve either Complete response (CR) or Partial response (PR).

- Disease control rate (DCR) [Time Frame: Weeks 24, 48 and at end of the study (up to approximately 102 weeks)]
  [Designated as safety issue: No]

  The DCR is defined as the rate of CR plus PR plus Stable Disease (SD). DCR evaluated according to RECIST v1.0

- Best overall response [Time Frame: At end of the study (up to approximately 102 weeks)] [Designated as safety issue: No]

  Best overall response according to RECIST v1.0 defined as the best response recorded from the initiation of treatment until disease progression

- Median duration of Stable Disease (SD) [Time Frame: Every 14 days up to approximately 102 weeks] [Designated as safety issue: No]

  Median duration of SD according to RECIST v1.0 defined as the time from first injection of lanreotide Autogel® 120 mg every 14 days until the first occurrence of progressive disease by central assessment

- Total number of stools and flushing episodes [Time Frame: During 1 week prior to visit until end of the study (up to approximately 102 weeks)]
  [Designated as safety issue: No]

  Symptom control (diarrhoea, flushing) as measured by the total number of stools and flushing episodes during the 7 days prior to the visit reported orally by the subject to the investigator.

- Change in Quality of life (QLQ-C30) from baseline [Time Frame: Every 12 weeks up to approximately 102 weeks]
  [Designated as safety issue: No]

  Change in Quality of life from baseline every 12 weeks measured using European Organisation into the Research and Treatment of Cancer (EORTC), Quality of Life Questionnaire Core 30 (QLQ-C30) v3.0.

- Change in Quality of life (QLQ-GI.NET21) from baseline [Time Frame: Every 12 weeks up to approximately 102 weeks]
  [Designated as safety issue: No]

  Change in Quality of life from baseline every 12 weeks measured using Quality of Life Questionnaire Gastrointestinal Neuroendocrine Tumour 21 (QLQ-GI.NET21; 2006)

- Change in Quality of life (EQ-5D-5L) from baseline [Time Frame: Every 12 weeks up to approximately 102 weeks]
  [Designated as safety issue: No]

  Change in Quality of life from baseline every 12 weeks measured using EuroQoL 5 dimensions, 5 levels (EQ-5D-5L) v1.0 questionnaire.

- Change in tumour biomarker concentrations from baseline [Time Frame: Baseline, Weeks 2 and 12 and every 12 weeks thereafter, up to approximately 102 weeks] [Designated as safety issue: No]

  Concentrations of non-specific (Chromogranin A, neuron specific enolase and 5-hydroxyindoleacetic acid) and specific tumour peptide biomarkers (e.g. pancreatic polypeptide, gastrin, glucagon, and somatostatin)

Estimated Enrollment:	100
Study Start Date:	November 2015
Estimated Study Completion Date:	October 2019
Estimated Primary Completion Date:	October 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Lanreotide Autogel® One subcutaneous (SC) injection of lanreotide Autogel® 120mg every 14 days until disease progression or death or unacceptable toxicity or tolerability.	Drug: Lanreotide autogel 120 mg

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histopathologically confirmed, grade 1 or 2, metastatic or locally advanced, unresectable pNET (pNET cohort) or midgut NET (midgut cohort) with or without hormone related syndromes, with a proliferation index (Ki67) ≤20%.
- Positive somatostatin receptors type 2
- Progression as assessed by an independent central reviewer according to RECIST v1.0 while receiving first line treatment with lanreotide Autogel® at a standard dose of 120 mg every 28 days for at least 24 weeks

Exclusion Criteria:

- Grade 3 or rapidly progressive (within 12 weeks) NET
- Any NET other than pancreatic and midgut
- Previous treatment with any antitumour agent for NET other than lanreotide Autogel® 120 mg every 28 days
- Gallbladder lithiasis at Screening echography or history of cholelithiasis with no cholecystectomy since then.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02651987

Contacts

Contact: Ipsen Recruitment Enquiries clinical.trials@ipsen.com

Locations

United States, Louisiana

Ochsner Medical Center - Kenner New Orleans, Louisiana, United States, 70121	**Not yet recruiting**

Belgium

Cliniques Unversitaires Saint Luc Bruxelles, Belgium, 1200	**Active, not recruiting**
UZ Leuven Leuven, Belgium, B-3000	**Active, not recruiting**

Denmark

Aarhus University Hospital Aarhus, Denmark	**Active, not recruiting**
Rigshospitalet København, Denmark, 2100	**Active, not recruiting**

France

Hôpital Beaujon Clichy, France, 92118	**Recruiting**
Hôpital Edouard Herriot Lyon, France, 69437	**Recruiting**
Institut Paoli Calmette Marseille, France, 13273	**Recruiting**

Germany

Charité - CVK Berlin, Germany, 13353	**Active, not recruiting**
Nationales Centrum für Tumorerkrankungen (NCT) Heidelberg, Germany, 69120	**Recruiting**

Ireland

St Vincent's University Hospital Dublin, Ireland, D4	**Recruiting**

Italy

Azienda Ospedaliera - Universitaria Careggi Firenze, Italy, 50134	**Active, not recruiting**
Fondacione IRCCS Istituto Nazionale Dei Tumori Milano, Italy, 20133	**Recruiting**
Università degli Studi "Federico II" di Napoli Napoli, Italy, 80131	**Active, not recruiting**
Azienda Ospedaliera sant'Andrea Roma, Italy, 00189	**Recruiting**

Netherlands

AVL/NKI Medisch Oncologie aMSTERDAM, Netherlands, 1066	**Active, not recruiting**
Academic Medical Center Amsterdam, Netherlands, 1105	**Recruiting**
Erasmus MC Rotterdam, Netherlands, 3015	**Recruiting**

Poland

Samodzielny Publiczny Szpital Kliniczny nr 5 Katowice, Poland, 40-952	**Recruiting**
Katedra i Klinika Endokrynologii Poznan, Poland, 60-355	**Recruiting**
Centrum Diagnostyczno- Lecznicze "Gammed" Warsaw, Poland, 02-348	**Recruiting**

Spain

Hospital Universitario Vall D'hebron Barcelona, Spain, 08034	**Recruiting**
Hospital Universitario Ramón Y Cajal Madrid, Spain, 28034	**Active, not recruiting**
Hospital Universitario 12 De Octubre Madrid, Spain, 28041	**Active, not recruiting**
Hospital Universitario Central de Asturias Oviedo, Spain, 33011	**Active, not recruiting**

United Kingdom

Queen Elizabeth Medical Center Birmingham, United Kingdom, B15 2TH	**Active, not recruiting**
Royal Free Hospital London, United Kingdom, NW3 2QG	**Recruiting**
The Christie Hospital NHS Foundation Trust Manchester, United Kingdom, M20 4BX	**Active, not recruiting**

Sponsors and Collaborators

Ipsen

Investigators

Study Director: Christine Massien, MD Ipsen

More Information

Responsible Party:	Ipsen
ClinicalTrials.gov Identifier:	NCT02651987 History of Changes
Other Study ID Numbers:	8-79-52030-326 2014-005607-24
Study First Received:	December 11, 2015
Last Updated:	October 24, 2016
Health Authority:	United Kingdom: Medicines and Healthcare Products Regulatory Agency Belgium: Federal Agency for Medicines and Health Products, FAMHP Denmark: Danish Health and Medicines Authority France: Agence Nationale de Sécurité du Médicament et des produits de santé Germany: Federal Institute for Drugs and Medical Devices Ireland: Health Products Regulatory Authority Italy: The Italian Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Spain: Agencia Española de Medicamentos y Productos Sanitarios United States: Food and Drug Administration

Additional relevant MeSH terms:

Neoplasms	Neoplasms by Site
Neuroendocrine Tumors	Endocrine Gland Neoplasms
Carcinoid Tumor	Digestive System Diseases
Pancreatic Neoplasms	Pancreatic Diseases
Neuroectodermal Tumors	Endocrine System Diseases
Neoplasms, Germ Cell and Embryonal	Lanreotide
Neoplasms by Histologic Type	Angiopeptin
Neoplasms, Nerve Tissue	Somatostatin
Adenocarcinoma	Antineoplastic Agents
Carcinoma	Hormones

Neoplasms, Glandular and Epithelial
Digestive System Neoplasms

Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on October 31, 2016