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Trial record **2 of 8** for: larotaxel

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Larotaxel Compared To Continuous Administration of 5-FU in Advanced Pancreatic Cancer Patients Previously Treated With A Gemcitabine-Containing Regimen (PAPRIKA)

This study has been completed.

Sponsor:
Sanofi

Information provided by (Responsible Party):
Sanofi

ClinicalTrials.gov Identifier:
NCT00417209

First received: December 28, 2006
Last updated: May 3, 2016
Last verified: May 2016
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to compare the efficacy and the safety **Larotaxel** administered as single agent every 3 weeks to continuous administration of 5-FU every 3 weeks, in patients with advanced pancreatic cancer (non operable in a curative intent, locally recurrent or metastatic) previously treated with gemcitabine based therapy.

Condition	Intervention	Phase
Pancreatic Neoplasms	Drug: **Larotaxel** (**XRP9881**) Drug: 5-Fluorouracil Drug: Capecitabine	Phase 3

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

Official Title: A Randomized, Open Label Multi-Center Study Of Single Agent **Larotaxel** (**XRP9881**) Compared To Continuous Administration of 5-FU For The Treatment Of Patients With Advanced Pancreatic Cancer Previously Treated With A Gemcitabine-Containing Regimen

Resource links provided by NLM:

MedlinePlus related topics: Cancer Pancreatic Cancer

Drug Information available for: Fluorouracil Capecitabine

Genetic and Rare Diseases Information Center resources: Pancreatic Cancer

U.S. FDA Resources

Further study details as provided by Sanofi:

Primary Outcome Measures:

- overall survival (OS) defined as the time interval from the date of randomization to the date of death due to any cause [Time Frame: study period] [Designated as safety issue: No]

Secondary Outcome Measures:

- Progression free survival (PFS); Overall Response Rate (proportion of patients with confirmed RECIST-defined complete response (CR) or partial response (PR); clinical benefit based on the measurement of tumor related symptoms; [Time Frame: study period]
  [Designated as safety issue: No]

Enrollment: 408
Study Start Date: December 2006
Study Completion Date: November 2009
Primary Completion Date: July 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **Larotaxel** (**XRP9881**)	Drug: **Larotaxel** (**XRP9881**) administered as a 1-hour IV infusion on Day 1 of every 3 weeks (q3w)
Active Comparator: 5-Fluorouracil or capecitabine Each Investigator must choose either IV 5-FU or oral capecitabine regimen before the first participant begins the study and has to consistently use the chosen regimen throughout the study for all participants treated at her/his site.	Drug: 5-Fluorouracil administered as IV infusion from Day 1 to Day 4 Drug: Capecitabine administered orally from Day 1 to Day 14 q3w

Eligibility

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

Criteria

Inclusion Criteria:

- Advanced (non operable in a curative intent, locally recurrent or metastatic disease) Cytologically or histologically proven epithelial cancer (adenocarcinoma) of the exocrine pancreas.
- Patient must be previously treated with a systemic gemcitabine based regimen
- Adequate bone marrow, kidney and liver functions

Exclusion Criteria:

- ECOG performance status (PS) of 2-3-4.
- Prior locoregional radiotherapy for pancreatic cancer.
- Symptomatic brain metastases or leptomeningeal disease.
- Any serious intercurrent infections, uncontrolled cardiac or gastro-intestinal diseases.
- Other concurrent malignancy
- Other protocol-defined exclusion/inclusion criteria may apply

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: NCT00417209

Show 21 Study Locations

Sponsors and Collaborators

Sanofi

Investigators

Study Director: ICD Sanofi

Responsible Party:	Sanofi
ClinicalTrials.gov Identifier:	NCT00417209 History of Changes
Other Study ID Numbers:	EFC6596 EUDRACT: 2006-003086-14
Study First Received:	December 28, 2006
Last Updated:	May 3, 2016
Health Authority:	United States: Food and Drug Administration United Kingdom: Medicines and Healthcare Products Regulatory Agency

Keywords provided by Sanofi:
advanced pancreatic cancer

Additional relevant MeSH terms:

Pancreatic Neoplasms
Digestive System Diseases
Digestive System Neoplasms
Endocrine Gland Neoplasms
Endocrine System Diseases
Neoplasms
Neoplasms by Site
Pancreatic Diseases
Capecitabine
Fluorouracil
Antimetabolites
Antimetabolites, Antineoplastic
Antineoplastic Agents
Immunologic Factors
Immunosuppressive Agents
Molecular Mechanisms of Pharmacological Action
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on June 19, 2016