Ex. E

A Study to Collect Survival Data on Patients Previously Enrolled in Abraxane Pancreatic Cancer Study CA046.

ClinicalTrials.gov Identifier: NCT02021500

Recruitment Status : Completed
First Posted : December 27, 2013
Last Update Posted : November 1, 2016

Sponsor:
Celgene Corporation

Information provided by (Responsible Party):
Celgene Corporation

Study Description

Go to

Brief Summary:

A study to collect survival data on patients previously enrolled in Abraxane pancreatic cancer study CA046.

Condition or disease	Intervention/treatment
Pancreatic Cancer	Drug: ABI-007

Detailed Description:

A study to collect survival status of CA046 subjects who were know to be alive at the last report of vital status for CA046 - approximate timeframe - end of March, 2013. Once consent is given, on a quarterly basis, information on status will be collected to include:

- Vital Status
- Date of disease progression
- Subsequent anticancer therapy for pancreatic adenocarcinoma

Study Design

Go to

Study Type : Observational
Actual Enrollment : 40 participants

Time Perspective:	Prospective
Official Title:	MPACT Extension Study: Multicenter, Survival Data Collection in Subjects Previously Enrolled in Protocol CA046
Study Start Date :	January 2014
Actual Primary Completion Date :	April 2015
Actual Study Completion Date :	April 2015

Resource links provided by the National Library of Medicine NIH NLM

MedlinePlus related topics: Pancreatic Cancer

Drug Information available for: Paclitaxel

Genetic and Rare Diseases Information Center resources: Pancreatic Cancer

U.S. FDA Resources

Groups and Cohorts

Go to

Group/Cohort	Intervention/treatment
Patients previously enrolled in study CA046 No intervention is being given in this extension study which is gathering survival information on participants of study NCT 00844649 (Celgene study CA046) who were known to be alive as of March 2013)	Drug: ABI-007 No intervention is being given in this extension study which is gathering survival information on participants of study NCT 00844649 (Celgene study CA046) who were known to be alive as of March 2013)

Outcome Measures

Go to

Primary Outcome Measures :

1. Overall Survival [Time Frame: up to 3 years]

   Number of participants who survive

Secondary Outcome Measures :

1. Disease progression [Time Frame: up to 3 years]

   Date of disease progression and subsequent anticancer therapy for pancreatic adenocarcinoma other than that already recorded for subject while enrolled in CA046

Eligibility Criteria

Go to

Information from the National Library of Medicine NIH NLM

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, Learn About Clinical Studies.

Ages Eligible for Study:	Child, Adult, Older Adult
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

Patients previously enrolled in study CA046

Criteria

Inclusion Criteria:

- Must have been enrolled in the CA046 study Must have been living at the time of the last survival follow-up (approximate timeframe - end of March, 2013) Must understand and be able to give informed consent (if a subject is deceased, proper legal consent (ie, next of kin, legal representative) will be obtained prior to collection of data)

Exclusion Criteria:

- Consent refused for any reason

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02021500***

Show 39 Study Locations

Sponsors and Collaborators

Celgene Corporation

Investigators

Study Director: Victoria Manax, MD Celgene

More Information

Go to

Publications:

Ramanathan RK, Goldstein D, Korn RL, Arena F, Moore M, Siena S, Teixeira L, Tabernero J, Van Laethem JL, Liu H, McGovern D, Lu B, Von Hoff DD. Positron emission tomography response evaluation from a randomized phase III trial of weekly nab-paclitaxel plus gemcitabine versus gemcitabine alone for patients with metastatic adenocarcinoma of the pancreas. Ann Oncol. 2016 Apr;27(4):648-53. doi: 10.1093/annonc/mdw020. Epub 2016 Jan 22.

Chiorean EG, Von Hoff DD, Reni M, Arena FP, Infante JR, Bathini VG, Wood TE, Mainwaring PN, Muldoon RT, Clingan PR, Kunzmann V, Ramanathan RK, Tabernero J, Goldstein D, McGovern D, Lu B, Ko A. CA19-9 decrease at 8 weeks as a predictor of overall survival in a randomized phase III trial (MPACT) of weekly nab-paclitaxel plus gemcitabine versus gemcitabine alone in patients with metastatic pancreatic cancer. Ann Oncol. 2016 Apr;27(4):654-60. doi: 10.1093/annonc/mdw006. Epub 2016 Jan 22.

Goldstein D, Von Hoff DD, Moore M, Greeno E, Tortora G, Ramanathan RK, Macarulla T, Liu H, Pilot R, Ferrara S, Lu B. Development of peripheral neuropathy and its association with survival during treatment with nab-paclitaxel plus gemcitabine for patients with metastatic adenocarcinoma of the pancreas: A subset analysis from a randomised phase III trial (MPACT). Eur J Cancer. 2016 Jan;52:85-91. doi: 10.1016/j.ejca.2015.10.017. Epub 2015 Dec 1.

Portal A, Pernot S, Tougeron D, Arbaud C, Bidault AT, de la Fouchardière C, Hammel P, Lecomte T, Dréanic J, Coriat R, Bachet JB, Dubreuil O, Marthey L, Dahan L, Tchoundjeu B, Locher C, Lepère C, Bonnetain F, Taieb J. Nab-paclitaxel plus gemcitabine for metastatic pancreatic adenocarcinoma after Folfirinox failure: an AGEO prospective multicentre cohort. Br J Cancer. 2015 Sep 29;113(7):989-95. doi: 10.1038/bjc.2015.328. Epub 2015 Sep 15.

Goldstein D, El-Maraghi RH, Hammel P, Heinemann V, Kunzmann V, Sastre J, Scheithauer W, Siena S, Tabernero J, Teixeira L, Tortora G, Van Laethem JL, Young R, Penenberg DN, Lu B, Romano A, Von Hoff DD. nab-Paclitaxel plus gemcitabine for metastatic pancreatic cancer: long-term survival from a phase III trial. J Natl Cancer Inst. 2015 Jan 31;107(2). pii: dju413. doi: 10.1093/jnci/dju413. Print 2015 Feb.

Vogel A, Pelzer U, Salah-Eddin AB, Köster W. First-line nab-paclitaxel and gemcitabine in patients with metastatic pancreatic cancer from routine clinical practice. In Vivo. 2014 Nov-Dec;28(6):1135-40.

Von Hoff DD, Ervin T, Arena FP, Chiorean EG, Infante J, Moore M, Seay T, Tjulandin SA, Ma WW, Saleh MN, Harris M, Reni M, Dowden S, Laheru D, Bahary N, Ramanathan RK, Tabernero J, Hidalgo M, Goldstein D, Van Cutsem E, Wei X, Iglesias J, Renschler MF. Increased survival in pancreatic cancer with nab-paclitaxel plus gemcitabine. N Engl J Med. 2013 Oct 31;369(18):1691-703. doi: 10.1056/NEJMoa1304369. Epub 2013 Oct 16.

Responsible Party:	Celgene Corporation
ClinicalTrials.gov Identifier:	NCT02021500 History of Changes
Other Study ID Numbers:	ABI-007-PANC-CA046C
First Posted:	December 27, 2013 Key Record Dates
Last Update Posted:	November 1, 2016
Last Verified:	October 2016

Additional relevant MeSH terms:

Pancreatic Neoplasms	Digestive System Diseases
Digestive System Neoplasms	Pancreatic Diseases
Neoplasms by Site	Endocrine System Diseases
Neoplasms	Albumin-Bound Paclitaxel
Endocrine Gland Neoplasms	Antineoplastic Agents