Nab-paclitaxel and Gemcitabine vs Gemcitabine Alone as Adjuvant Therapy for Patients With Resected Pancreatic Cancer (the "Apact" Study) (apact)

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

Verified October 2014 by Celgene Corporation

Sponsor:
Celgene Corporation

Information provided by (Responsible Party):
Celgene Corporation

ClinicalTrials.gov Identifier: NCT01964430

First received: October 14, 2013
Last updated: October 3, 2014
Last verified: October 2014

Purpose

The purpose of this study is to compare whether there is a delay or prevention of recurrence or death in subjects with surgically removed pancreatic cancer who then take nab-paclitaxel in combination with gemcitabine compared to those who take gemcitabine alone.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic Neoplasms</td>
<td>Drug: nab-Paclitaxel 125 mg/m2</td>
<td>Phase 3</td>
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<tr>
<td>Digestive System Neoplasms</td>
<td>Drug: gemcitabine 1000 mg/m2</td>
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<tr>
<td>Neoplasms by Site</td>
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<tr>
<td>Neoplasms</td>
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<tr>
<td>Endocrine Gland Neoplasms</td>
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<tr>
<td>Pancreatic Diseases</td>
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<tr>
<td>Digestive System Diseases</td>
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<tr>
<td>Endocrine System Diseases</td>
<td></td>
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<tr>
<td>Gemcitabine</td>
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<tr>
<td>Antimetabolites, Antineoplastic</td>
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</tbody>
</table>

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

Official Title: A Phase 3, Multicenter, Open-label, Randomized Study of Nab-Paclitaxel Plus Gemcitabine Versus Gemcitabine Alone as Adjuvant Therapy in Subjects With Surgically Resected Pancreatic Adenocarcinoma

Resource links provided by NLM:

- MedlinePlus related topics: Cancer, Digestive Diseases, Endocrine Diseases, Pancreatic Cancer, Pancreatic Diseases
- Drug Information available for: Paclitaxel, Gemcitabine, Gemcitabine hydrochloride
- Genetic and Rare Diseases Information Center resources: Pancreatic Cancer
- U.S. FDA Resources

Further study details as provided by Celgene Corporation:
Primary Outcome Measures:
- Disease Free Survival (DFS) [Time Frame: up to approximately 9 months] [Designated as safety issue: No]
  Time from the date of randomization to the date of disease recurrence or death, whichever is earlier. (Disease recurrence will be determined by independent radiological review of computed tomography (CT) or magnetic resonance imaging (MRI) scans.)

Secondary Outcome Measures:
- Overall Survival [Time Frame: up to approximately 18 months] [Designated as safety issue: No]
  Time from the date of randomization to the date of death
- Number of Participants with Adverse Events [Time Frame: up to approximately 18 months] [Designated as safety issue: Yes]
  Assessment based on AEs, SAEs, laboratory abnormalities.

Estimated Enrollment: 800
Study Start Date: March 2014
Estimated Study Completion Date: October 2020
Estimated Primary Completion Date: April 2019 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
</table>
| Experimental: *nab-Paclitaxel* 125 mg/m² plus gemcitabine 1000 mg/m² | Drug: *nab-Paclitaxel* 125 mg/m²  
  *nab-Paclitaxel* 125 mg/m² on Days 1, 8, and 15 of a 28 day cycle by intravenous (IV) administration, followed by gemcitabine 1000 mg/m² on Days 1, 8, and 15 of a 28 days cycle by IV administration for a total of 6 cycles  
  Other Name: *Abraxane*  
  Drug: gemcitabine 1000 mg/m²  
  *nab-Paclitaxel* 125 mg/m² on Days 1, 8, and 15 of a 28 day cycle by intravenous (IV) administration, followed by gemcitabine 1000 mg/m² on Days 1, 8, and 15 of a 28 days cycle by IV administration for a total of 6 cycles  
  Other Name: Gemzar |
| Treatment Arm A            |                                                                                       |
| Active Comparator: Gemcitabine 1000 mg/m² | Drug: gemcitabine 1000 mg/m²  
  Gemcitabine 1000 mg/m² on Days 1, 8, and 15 of a 28 day cycle by IV administration for a total of 6 cycles  
  Other Name: Gemzar |
| Treatment Arm B            |                                                                                       |

Detailed Description:
ABI-007-PANC-003 is a Phase 3, international, multicenter, randomized, open-label, controlled study that will compare the efficacy of nab-paclitaxel in combination with gemcitabine to gemcitabine alone as adjuvant treatment for 6 cycles in patients with surgically resected pancreatic adenocarcinoma.

Eligibility

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

Criteria
Inclusion Criteria:
1. Histologically confirmed resected ductal pancreatic adenocarcinoma with macroscopic complete resection (R0 and R1). Subjects with neuroendocrine (and mixed type) tumors are excluded.
2. Pancreatic cancer surgical staging: T 1-3, N0-1, M0.
3. Subject should be able to start treatment no later than 12 weeks postsurgery.
4. ≥18 years of age at the time of signing the informed consent form (ICF).
5. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
6. Acceptable hematology parameters:
Absolute neutrophil count ≥1500 cell/mm³
Platelet count ≥100,000/mm³
Hemoglobin (Hgb) ≥9 g/dL

7. Acceptable blood chemistry levels:
   - Aspartate aminotransferase (AST) / Serum glutamic oxaloacetic transaminase (SGOT) and Alanine transaminase (ALT) / Serum glutamic-pyruvic transaminase (SGPT) ≤2.5 × upper limit of normal range (ULN)
   - Total bilirubin ≤ Upper Limit of Normal (ULN) (subjects with Gilbert's syndrome can have bilirubin of up to 1.5 x ULN)
   - Alkaline phosphatase ≤ 2.5 × ULN
   - Serum creatinine within upper limits of normal or calculated clearance ≥50 mL/min/1.73 m². If using creatinine clearance, actual body weight should be used for calculating creatinine clearance (eg, using the Cockroft-Gault formula). For subjects with a Body Mass Index (BMI) >30 kg/m², lean body weight should be used instead.
   - Cancer antigen (CA)19-9 <100 U/mL assessed within 14 days of randomization
   - Acceptable coagulation studies as demonstrated by Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) within normal limits (±15%)

Exclusion Criteria:
A subject will not be eligible for inclusion in this study if any of the following criteria apply:
1. Prior neo-adjuvant treatment or radiation therapy for pancreatic adenocarcinoma
2. Presence of or history of metastatic pancreatic adenocarcinoma
3. Any other malignancy within 5 years prior to randomization, with the exception of adequately treated in-situ carcinoma of the cervix, uteri, or nonmelanomatous skin cancer (all treatment of which should have been completed 6 months prior to randomization)
4. Active, uncontrolled bacterial, viral, or fungal infection(s) requiring systemic therapy, defined as ongoing signs/symptoms related to the infection without improvement despite appropriate antibiotics, antiviral therapy, and/or other treatment
5. Known infection with hepatitis B or C, or history of human immunodeficiency virus (HIV) infection, or subject receiving immunosuppressive or myelosuppressive medications that would in the opinion of the investigator, increase the risk of serious neutropenic complications
6. History of allergy or hypersensitivity to nab-paclitaxel or gemcitabine or any of their excipients
7. Serious medical risk factors involving any of the major organ systems, or serious psychiatric disorders, which could compromise the subject's safety or the study data integrity. These include, but are not limited to:
   a. History of connective tissue disorders (eg, lupus, scleroderma, arthritis nodosa)
   b. History of interstitial lung disease, slowly progressive dyspnea and unproductive cough, sarcoidosis, silicosis, idiopathic pulmonary fibrosis, pulmonary hypersensitivity pneumonitis or multiple allergies
   c. History of the following within 6 months prior to Cycle 1 Day 1: a myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, New York Heart Association (NYHA) Class III-IV heart failure, uncontrolled hypertension, clinically significant cardiac dysrhythmia or ECG abnormality, cerebrovascular accident, transient ischemic attack, or seizure disorder

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: NCT01964430

Contacts
Contact: Associate Director Clinical Trial Disclosure 1-888-260-1599 clinicaltrialdisclosure@celgene.com

Show 173 Study Locations

Sponsors and Collaborators
Celgene Corporation

Investigators
Study Director: Ileana Elias, M.D. Celgene Corporation

More Information
Responsible Party: Celgene Corporation
ClinicalTrials.gov Identifier: NCT01964430
Other Study ID Numbers: ABI-007-PANC-003, 2013-003398-91
Study First Received: October 14, 2013
Last Updated: October 3, 2014
Health Authority: Australia: Department of Health and Aging Therapeutic Good Administration
Austria: Austrian Medicines and Medical Devices Agency
Belgium: Federal Agency for Medicines and Health Products, FAMHP
Canada: Health Canada
Czech Republic: State Institute for Drug Control
Denmark: Danish Health and Medicines Authority
Finland: Finnish Medicines Agency
France: National Agency for the Safety and Medicine and Health Products
Germany: Federal Institute for Drugs and Medical Devices
Hong Kong: Department of Health
Hungary: National Institute of Pharmacy
Italy: Ministry of Health
Portugal: National Pharmacy and Medicines Institute
Singapore: Health Sciences Authority
Spain: Spanish Agency for Medicines and Health Products
Taiwan: Taiwan Food and Drug Administration
United Kingdom: Medicines and Healthcare Products Regulatory Agency
United States: Food and Drug Administration

Keyw ords provided by Celgene Corporation:

Abraxane
nab-paclitaxel
ABI-007
Resectable pancreatic cancer
resected
resectable PDA

adenocarcinoma
surgically resected
adjuvant
gemcitabine
Gemzar
Phase 3

Additional relevant MeSH terms:

Paclitaxel
Digestive System Diseases
Endocrine Gland Neoplasms
Endocrine System Diseases
Gastrointestinal Diseases
Gastrointestinal Neoplasms
Neoplasms
Neoplasms by Site
Pancreatic Diseases
Pancreatic Neoplasms
Gemcitabine
Anti-Infective Agents
Antimetabolites
Antimetabolites, Antineoplastic

Antimitotic Agents
Antineoplastic Agents
Antineoplastic Agents, Phytogenic
Antiviral Agents
Enzyme Inhibitors
Immunologic Factors
Immunosuppressive Agents
Mitosis Modulators
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
Radiation-Sensitizing Agents
Therapeutic Uses
Tubulin Modulators

ClinicalTrials.gov processed this record on November 17, 2014