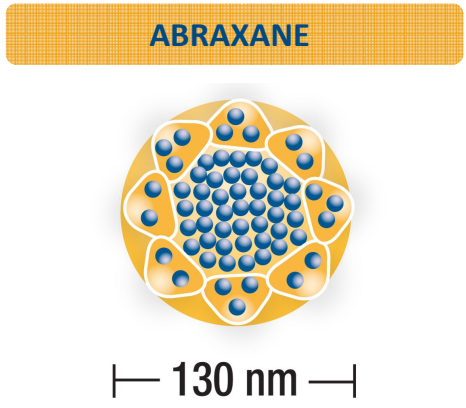
Abraxane® for Injectable Suspension
(paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

FACT SHEET

- BRANDED/GENERIC NAME: ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)
- ABRAXANE is an albumin-bound form of paclitaxel with a mean particle size of approximately 130 nanometers that is delivered as an intravenous infusion
- ABRAXANE is a prescription medication approved by the U.S. Food and Drug Administration to treat the following:
  - breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. FDA-approved in January 2005.
  - the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC), in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. FDA-approved in October 2012.
  - the first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine. FDA-approved in September 2013
- ABRAXANE has been globally approved in more than forty countries for the treatment of metastatic breast cancer (MBC). ABRAXANE is also approved for the treatment of advanced NSCLC in Argentina, Australia, Japan, and New Zealand
- ABRAXANE is manufactured using patented *nab*® technology
- ABRAXANE is formulated with albumin – a human protein found in the blood
- ABRAXANE is free of chemical solvents
- ABRAXANE disrupts the internal support structure of cells, which is believed to interfere with their growth
- ABRAXANE is administered intravenously in approximately 30 to 40 minutes depending on the tumor-type it is being used to treat
- ABRAXANE is provided in single-use vials containing 100 mg of paclitaxel for reconstitution



ABRAXANE, shown in this conceptualization, is approximately 130 nm (nanometers) particle of paclitaxel (blue) coated in albumin (yellow).

Please see **full Prescribing Information, including Boxed WARNING, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.**

Abraxane®
for Injectable Suspension
(paclitaxel protein-bound particles for injectable suspension)
(albumin-bound)

Efficacy, Safety and Dose of ABRAXANE in Metastatic Breast Cancer

- ABRAXANE is used to treat advanced breast cancer in people who have already received certain other medicines for their cancer or when the cancer has come back within 6 months of treatment after surgery. The effectiveness and safety of ABRAXANE were studied in a phase III clinical trial with 460 patients with metastatic breast cancer. In the study, 233 patients were chosen at random to receive ABRAXANE, and 227 patients received a medicine called paclitaxel injection:
  - Patients were more likely to have their tumors shrink with ABRAXANE (21.5%) compared with paclitaxel (11.1%). There was no significant difference in length of survival between the two study arms in the trial. In those patients in the trial who had combination chemotherapy that had stopped working or had their cancer come back within 6 months of treatment after surgery, there was no significant difference in the rates of tumor shrinkage between those treated with ABRAXANE and those treated with paclitaxel injection.
- The most common adverse reactions (≥ 20%) with ABRAXANE were alopecia, neutropenia, sensory neuropathy, abnormal ECG, fatigue/asthenia, myalgia/arthralgia, AST elevation, alkaline phosphatase elevation, anemia, nausea, diarrhea and infections.
- The recommended regimen for ABRAXANE in MBC is 260 mg/m^2 administered intravenously over 30 minutes every 3 weeks. Recommended dose modifications for certain serious adverse reactions are included in the prescribing information.

Efficacy, Safety and Dose of ABRAXANE in Locally Advanced or Metastatic Non-small Cell Lung Cancer

- ABRAXANE is used in combination with carboplatin to treat advanced non-small cell lung cancer (NSCLC) in people who cannot be treated with surgery or radiation. The effectiveness and safety of ABRAXANE were studied in an open-label phase III clinical trial of 1,052 patients with advanced NSCLC who did not previously receive chemotherapy:
  - Patients were more likely to have their tumors shrink with ABRAXANE and carboplatin (33%) compared with paclitaxel injection and carboplatin (25%). There was no statistically significant difference in the length of survival of patients in the two study arms in the trial.
  - The overall response rate for the ABRAXANE and carboplatin arm was 41% for squamous cell carcinoma and 33% for large cell carcinoma as compared to the paclitaxel and carboplatin arm, 24% and 15%, respectively.
- The most common adverse reactions (≥20%) for ABRAXANE in combination with carboplatin were anemia, neutropenia, thrombocytopenia, alopecia, peripheral neuropathy, nausea, and fatigue.
- The recommended dose of ABRAXANE is 100 mg/m^2 administered as an intravenous infusion over 30 minutes on Days 1, 8, and 15 of each 21-day cycle. The recommended dose of carboplatin is AUC = 6 mg•min/mL on Day 1 only of each 21-day cycle, beginning immediately after the completion of ABRAXANE administration. Recommended dose modifications for certain serious adverse reactions are included in the prescribing information.

Efficacy, Safety and Dose of ABRAXANE in Metastatic Pancreatic Cancer

- ABRAXANE is used to treat advanced pancreatic cancer, when used in combination with gemcitabine as the first medicine you receive for pancreatic cancer. The effectiveness and safety of ABRAXANE were studied in a pivotal phase III clinical trial titled “MPACT” -**M**etastatic **P**ancreatic **A**denocarcinoma **C**linical **T**rial - that involved 861 patients who had not previously received chemotherapy treatment:
  - Some patients who took ABRAXANE plus gemcitabine lived longer than patients who received gemcitabine alone. Patients treated with ABRAXANE plus gemcitabine lived a median of 8.5 months, compared with a

median of 6.7 months for those who were treated with gemcitabine alone; a 28% overall reduction in risk of death.

- ABRAXANE plus gemcitabine showed a statistically significant improvement in Progression-Free Survival (PFS) compared with patients treated with gemcitabine alone (median PFS of 5.5. vs. 3.7 months); a 31% reduction in the risk of patients either dying or having their disease worsen.

- The most common adverse reactions (≥20%) with a ≥5% higher incidence with the combination are neutropenia, fatigue, peripheral neuropathy, nausea, alopecia, peripheral edema, diarrhea, pyrexia, vomiting, decreased appetite, rash, and dehydration.
- The recommended dose of ABRAXANE is 125 mg/m^2 administered as an intravenous infusion over 30-40 minutes on Days 1, 8 and 15 of each 28-day cycle. The recommended dose of gemcitabine is 1000 mg/m^2 as an intravenous infusion over 30-40 minutes beginning immediately after the completion of ABRAXANE administration on Days 1, 8 and 15 of each 28-day cycle. Recommended dose modifications for certain serious adverse reactions are included in the prescribing information.

ABRAXANE® is a prescription medicine used to treat advanced breast cancer in people who have already received certain other medicines for their cancer or when the cancer has come back within 6 months of treatment after surgery.

ABRAXANE is a prescription medicine used in combination with carboplatin to treat advanced non–small cell lung cancer in people who cannot be treated with surgery or radiation.

ABRAXANE is a prescription medicine used to treat advanced pancreatic cancer, when used in combination with gemcitabine as the first medicine you receive for advanced pancreatic cancer.

Important Safety Information about ABRAXANE

WARNING: LOW WHITE BLOOD CELL COUNT (NEUTROPENIA)

Do not take ABRAXANE if your white blood cell count is below 1,500 cells/mm^3 (neutropenia), since you may be more likely to get a serious infection. While taking ABRAXANE, you must get regular blood tests to check for any problems that could develop.

ABRAXANE contains albumin, a substance found in human blood. Do not substitute for or with other paclitaxel formulations.

- Allergic reactions to ABRAXANE may be severe and can lead to death. In case of severe allergic reaction, ABRAXANE should not be used again.

- ABRAXANE can cause a severe decrease in neutrophils (a type of white blood cells important in fighting against bacterial infections) and platelets (important for clotting and to control bleeding). Your doctor will check your blood cell count during your treatment with ABRAXANE and after you have stopped your treatment.

- People treated with ABRAXANE often have numbness, tingling, pain or weakness in the hands or feet (neuropathy).

- If you receive ABRAXANE in combination with gemcitabine, you may experience severe infections (sepsis) that can lead to death. Tell your doctor right away if you have a fever (temperature of greater than 100.4° F) or develop signs of infection.

- If you receive ABRAXANE in combination with gemcitabine, lung or breathing problems may be severe and can lead to death. Tell your doctor right away if you have a sudden onset of persistent dry cough or shortness of breath.

- Treatment with ABRAXANE can make liver problems worse. If you have liver problems, your starting dose of ABRAXANE should be lowered.

- ABRAXANE contains albumin (human), a product of human blood.

- If you are pregnant, or become pregnant, ABRAXANE can harm your unborn baby. You should not become pregnant while taking ABRAXANE. Women who may become pregnant should use effective birth control (contraception). Talk to your doctor about the best way to prevent pregnancy while receiving ABRAXANE.

- If you are a man, you should not father a child during your treatment with ABRAXANE. ABRAXANE can harm the unborn baby of your partner. Talk to your doctor if this is a concern to you.

The most common side effects of ABRAXANE include:

- Hair loss
- Numbness, tingling, pain, or weakness in the hands or feet
- Abnormal heart beat
- Tiredness
- Joint and muscle pain
- Changes in your liver function tests
- Rash
- Low red blood cell count (anemia). Red blood cells carry oxygen to your body tissues. Tell your doctor if you feel weak, tired or short of breath.
- Nausea and Vomiting
- Infections. If you have a fever (temperature of greater than 100.4º F) or other signs of infection, tell your doctor right away.
- Diarrhea
- Loss of body fluid (dehydration)
- Swelling in the hands or feet

- Other side effects included vision problems, decreased appetite, kidney problems, constipation, difficulty breathing, and allergic reactions.

- In some patients receiving ABRAXANE, severe heart and blood vessel side effects have occurred. These included chest pain, heart attack, fluid under the skin, blood clots in the veins or lungs, high blood pressure, stroke and heart failure.

- You should contact your doctor if you have signs or symptoms of vomiting, diarrhea, dehydration, cough or breathing difficulties that do not go away, or signs of an allergic reaction. Tell your doctor if you have any other medical conditions.

- Treatment with ABRAXANE can cause irritation where the medicine is injected (injection site reactions). You

should be monitored by your doctor or nurse during and after you receive ABRAXANE to make sure no problems occur at the injection site. In some cases, these problems occurred 7 to 10 days after the medicine was injected.

- It is not known whether ABRAXANE interacts with other drugs, so be sure to tell your doctor about any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements you are taking. Know the medicines you take. Keep a list to show your doctor and pharmacist when you get a new medicine.

- Since it is not known if ABRAXANE passes into human milk, you should discuss with your doctor if you should receive ABRAXANE or breastfeed.

- It is not known if ABRAXANE is safe or effective in children.

- ABRAXANE has not been studied in people with kidney problems.

These are not all the possible side effects of ABRAXANE. For more information, ask your doctor or pharmacist. You may report side effects to FDA at 1-800-FDA-1088

Please see full Prescribing Information, including Boxed WARNING
http://www.celgene.com/pdfs/ABRAXANE_PI.pdf