For the woman who has been through surgery, radiation, and chemotherapy —and is still fighting.



ABRAXANE® for Injectable Suspension is indicated for the treatment of 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.

Please see Black Box Warning; Important Safety Information; and Warnings, Precautions, and Contraindications below.

# ABRAXANE, the albumin-bound paclitaxel, can offer

## Nearly double the overall response rate vs solvent-based paclitaxel<sup>1</sup>

In the pivotal phase III trial

- 21.5% vs 11.1% (*P*=.003) for all study patients; 15.5% vs 8.4% (*P*=NS) for study patients who failed combination chemotherapy or relapsed within 6 months of adjuvant chemotherapy<sup>1</sup>

## **Delivery of a higher dose**

- Allows delivery of a 49% higher dose of paclitaxel without compromising safety and tolerability<sup>1</sup>
- 78% increase in median total paclitaxel dose delivered with ABRAXANE in the phase III clinical trial<sup>2</sup>

## The ability to simplify her treatment

Eliminates need for premedication for solvent-related hypersensitivity reactions;
 no need for special IV tubing: 30-minute infusion time vs solvent-based paclitaxel<sup>1</sup>

## **Recommended dosing**

 The recommended regimen for ABRAXANE for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) is 260 mg/m² administered intravenously over 30 minutes every 3 weeks¹

## **ARC of Support™ Reimbursement Services**

 Reimbursement information, claims appeals and reviews, benefit verification, prior authorization assistance, help for insured and uninsured patients through the Abraxis Patient Access Program (APAP)

1.800.564.0216 (Press 3),
Monday through Friday from 8 AM TO 8 PM Eastern Time



#### For more information, visit www.abraxane.com

Click on link for full Prescribing Information for ABRAXANE:
www.abraxane.com/resources/Abraxane Healthcare Prescribing Information.pdf



(paclitaxel protein-bound particles for injectable suspension (albumin-bound)

**BOUND AND DETERMINED** 

## **Resources:**

We are pleased to provide the following links to Web sites that you may find helpful. To visit any of these sites, click on the site name.

The Web sites listed below are neither owned nor controlled by Abraxis Oncology or AstraZeneca Pharmaceuticals. Abraxis Oncology and AstraZeneca Pharmaceuticals are not responsible for the content or services on these sites.

- National Comprehensive Cancer Network: www.nccn.org
- American Cancer Society: www.cancer.org
- P&T Community: www.formkit.com
- American Association for Cancer Research: www.aacr.org
- Clinical Trials: www.clinicaltrials.gov
- National Cancer Institute: www.nci.nih.gov
- Cancer Care: www.cancercare.org
- Living Beyond Breast Cancer: www.lbbc.org
- Sisters Network: www.sistersnetworkinc.com
- Metastatic Breast Cancer Network: www.mbcnetwork.org
- Y-ME National Breast Cancer Organization: www.y-me.org
- Susan G. Komen Breast Cancer Foundation: www.komen.org

#### For more information, visit www.abraxane.com

Click on link for full Prescribing Information for ABRAXANE: www.abraxane.com/resources/Abraxane\_Healthcare\_Prescribing\_Information.pdf Please see Black Box Warning; Important Safety Information; and Warnings, Precautions, and Contraindications below.



(paclitaxel protein-bound particles for injectable suspension (albumin-bound)

**BOUND AND DETERMINED** 

WARNING: ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available.

ABRAXANE therapy should not be administered to patients with metastatic breast cancer who have baseline neutrophil counts of less than 1,500 cells/mm<sup>3</sup>. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving ABRAXANE.

Note: An albumin form of paclitaxel may substantially affect a drug's functional properties relative to those of drug in solution. DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS.

#### IMPORTANT SAFETY INFORMATION

In the randomized metastatic breast cancer study, the most important adverse events included neutropenia (all cases 80%; severe 9%), anemia (all 33%; severe 1%), infections (24%), sensory neuropathy (any symptoms 71%; severe 10%), nausea (any 30%; severe 3%), vomiting (any 18%; severe 4%), diarrhea (any 27%; severe <1%), myalgia/arthralgia (any 44%; severe 8%), and mucositis (any 7%; severe <1%). Other adverse reactions included asthenia (any 47%; severe 8%), ocular/visual disturbances (any 13%; severe 1%), fluid retention (any 10%; severe 0%), alopecia (90%), hepatic dysfunction (elevations in bilirubin 7%, alkaline phosphatase 36%, AST [SGOT] 39%), and renal dysfunction (any 11%; severe 1%). Thrombocytopenia (any 2%; severe <1%), hypersensitivity reactions (any 4%; severe 0%), cardiovascular reactions (severe 3%), and injection site reactions (<1%) were uncommon. During postmarketing surveillance, rare occurrences of severe hypersensitivity reactions have been reported with ABRAXANE.

#### WARNINGS, PRECAUTIONS, AND CONTRAINDICATIONS

The use of ABRAXANE has not been studied in patients with hepatic or renal dysfunction. In the randomized controlled trial, patients were excluded for baseline serum bilirubin >1.5 mg/dL or baseline serum creatinine >2 mg/dL.

ABRAXANE can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with ABRAXANE.

Men should be advised to not father a child while receiving treatment with ABRAXANE.

ABRAXANE contains albumin (human), a derivative of human blood.

Caution should be exercised when administering ABRAXANE concomitantly with known substrates or inhibitors of CYP2C8 and CYP3A4.

ABRAXANE therapy should not be administered to patients with metastatic breast cancer who have baseline neutrophil counts of less than 1,500 cells/mm³. It is recommended that frequent peripheral blood cell counts be performed on all patients receiving ABRAXANE. Patients should not be retreated with subsequent cycles of ABRAXANE until neutrophils recover to a level >1,500 cells/mm³ and platelets recover to a level >100,000 cells/mm³.

In the case of severe neutropenia (<500 cells/mm³ for 7 days or more) during a course of ABRAXANE therapy, a dose reduction for subsequent courses is recommended.

Sensory neuropathy occurs frequently with ABRAXANE. The occurrence of grade 1 or 2 sensory neuropathy does not generally require dose modification. If grade 3 sensory neuropathy develops, treatment should be withheld until resolution to grade 1 or 2 followed by a dose reduction for all subsequent courses of ABRAXANE.

It is recommended that nursing be discontinued when receiving ABRAXANE therapy.

Severe cardiovascular events possibly related to single-agent ABRAXANE occurred in approximately 3% of patients in the randomized trial. These events included chest pain, cardiac arrest, supraventricular tachycardia, edema, thrombosis, pulmonary thromboembolism, pulmonary embolism, and hypertension.

#### **Click on link for full Prescribing Information for ABRAXANE:**

www.abraxane.com/resources/Abraxane\_Healthcare\_Prescribing\_Information.pdf

**REFERENCES:** 1. ABRAXANE [prescribing information]. Los Angeles, Calif: Abraxis Oncology, a Division of Abraxis BioScience, Inc.; May 2007. 2. Data on file, DA-ABR-01. Abraxis BioScience, Inc.

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(paclitaxel protein-bound particles for injectable suspension) (albumin-bound)

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