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MEDIA RELEASE

Sandoz US launches generic paclitaxel in single-dose vial, further expanding US oncology portfolio

- First FDA-approved abbreviated new drug application (ANDA) to reference medicine
- Single-dose 100 mg vial for intravenous use, approved for metastatic breast cancer
- Launch expected to be near-term growth driver in US market

Princeton, NJ, October 11, 2024 – Sandoz, the global leader in generic and biosimilar medicines, today announced that it has launched a generic paclitaxel formulation in the US, the first generic to its reference medicine to be approved by the US Food and Drug Administration (FDA).

Sandoz paclitaxel protein-bound particles for injectable suspension (albumin-bound) is indicated for the treatment of patients with metastatic breast cancer. The launch of the lyophilized powder for injection containing 100 mg of paclitaxel in a single-dose vial for intravenous use follows approval by the FDA on October 8, 2024.

"An estimated 168,000 women in the US are living with metastatic breast cancer.[1] While rare, men can also develop metastatic breast cancer.[2] This milestone is another proof point of our commitment to provide access to life-changing medicines for all who need them."

Keren Haruvi,
President,
Sandoz North America

Sandoz paclitaxel protein-bound particles for injectable suspension (albumin-bound) was developed in partnership with Jiangsu Hengrui Pharmaceuticals Co., Ltd., and is the first FDA-approved ANDA to reference product Abraxane®* for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension, albumin-bound).

*Abraxane® is a registered trademark of Abraxis BioScience LLC, a Bristol-Myers Squibb Company.

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

INDICATIONS
Paclitaxel protein-bound particles for injectable suspension (albumin-bound) is a microtubule inhibitor indicated for the treatment of: Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SEVERE MYELOSUPPRESSION
See full prescribing information for complete boxed warning.

- **Do not administer paclitaxel protein-bound particles for injectable suspension (albumin-bound) therapy to patients with baseline neutrophil counts of less than 1,500 cells/mm^3.**
- **Monitor for neutropenia, which may be severe and result in infection or sepsis.**
- **Perform frequent complete blood cell counts on all patients receiving paclitaxel protein-bound particles for injectable suspension (albumin-bound).**

CONTRAINDICATIONS
Neutrophil counts of < 1,500 cells/mm^3; and severe hypersensitivity reactions to paclitaxel protein-bound particles for injectable suspension (albumin-bound).

WARNINGS AND PRECAUTIONS
Sensory neuropathy occurs frequently and may require dose reduction or treatment interruption. Sepsis occurred in patients with or without neutropenia who received paclitaxel protein-bound particles for injectable suspension (albumin-bound) in combination with gemcitabine; interrupt paclitaxel protein-bound particles for injectable suspension (albumin-bound) and gemcitabine until sepsis resolves, and if neutropenia, until neutrophils are at least 1,500 cells/mm^3, then resume treatment at reduced dose levels. Pneumonitis occurred with the use of paclitaxel protein-bound particles for injectable suspension (albumin-bound) in combination with gemcitabine; permanently discontinue treatment with paclitaxel protein-bound particles for injectable suspension (albumin-bound) and gemcitabine. Severe hypersensitivity reactions with fatal outcome have been reported. Do not rechallenge with this drug. Exposure and toxicity of paclitaxel can be increased in patients with hepatic impairment, consider dose reduction and closely monitor patients with hepatic impairment. Paclitaxel protein-bound particles for injectable suspension (albumin-bound) contains albumin derived from human blood, which has a theoretical risk of viral transmission. Paclitaxel protein-bound particles for injectable suspension (albumin-bound) can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS
The most common adverse reactions (≥ 20%) in metastatic breast cancer are alopecia, neutropenia, sensory neuropathy, abnormal ECG, fatigue/asthenia, myalgia/arthralgia, AST elevation, alkaline phosphatase elevation, anemia, nausea, infections, and diarrhea.

DRUG INTERACTIONS
Use caution when concomitantly administering paclitaxel protein-bound particles for injectable suspension (albumin-bound) with inhibitors or inducers of either CYP2C8 or CYP3A4.

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USE IN SPECIFIC POPULATIONS
Lactation: Advise not to breastfeed.

This is not the complete list of all the safety information for Paclitaxel protein-bound particles for injectable suspension (albumin-bound). Please click to see the full Prescribing Information for Paclitaxel protein-bound particles for injectable suspension (albumin-bound).

DISCLAIMER

This Media Release contains forward-looking statements, which offer no guarantee with regard to future performance. These statements are made on the basis of management's views and assumptions regarding future events and business performance at the time the statements are made. They are subject to risks and uncertainties including, but not confined to, future global economic conditions, exchange rates, legal provisions, market conditions, activities by competitors and other factors outside of the control of Sandoz. Should one or more of these risks or uncertainties materialize or should underlying assumptions prove incorrect, actual outcomes may vary materially from those forecasted or expected. Each forward-looking statement speaks only as of the date of the particular statement, and Sandoz undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

References

[1] National Institutes of Health. NIH MedlinePlus Magazine. Quick Facts on Metastatic Breast Cancer. Available at Quick facts on metastatic breast cancer | NIH MedlinePlus Magazine. [Last accessed: September 2024]

[2] American Cancer Society. Treatment of Breast Cancer in Men, by Stage. Available at Treatment of Breast Cancer in Men, by Stage | American Cancer Society. [Last accessed: September 2024]

ABOUT SANDOZ

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of 100 nationalities work together to ensure 800 million patient treatments are provided by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,500 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2023, Sandoz recorded sales of USD 9.6 billion.

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