

Drugs recently approved or pending approval

ABRAXANE

The US Food and Drug Administration (FDA) has given approval to American Pharmaceutical Partners, Inc. (Schaumburg, IL) to market Abraxane (paclitaxel protein-bound particles for injectable suspension) for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Abraxane contains no toxic solvents, which enables the administration of 50% more chemotherapy, no premedication to prevent hypersensitivity reactions, and administration over 30 minutes using standard intravenous tubing. Abraxane was evaluated in a multicenter randomized trial involving 460 patients with metastatic breast cancer. Patients were randomized to Abraxane 260 mg/m² given as a 30-minute infusion or paclitaxel 175 mg/m² injection given as a 3-hour infusion. 14% of study patients had not received prior chemotherapy, 27% had received chemotherapy in the adjuvant setting, 40% had received chemotherapy in the metastatic setting, and 19% had received chemotherapy in both adjuvant and metastatic settings. Abraxane-treated patients had a statistically significantly higher reconciled target lesion response rate compared with patients in the paclitaxel injection arm (21.5% versus 11.1%; $P = 0.003$). The most common adverse effects seen with Abraxane were alopecia, neutropenia, sensory neuropathy, and abnormal electrocardiogram. The recommended dosage of Abraxane is 260 mg/m² administered intravenously over 30 minutes every 3 weeks.



PRIALT

The FDA has given approval to Elan Pharmaceuticals, Inc. (San Diego, CA) to market Prialt (ziconotide intrathecal [IT] infusion) for the management of severe chronic pain in patients for whom IT therapy is warranted and who are intolerant of or refractory to other treatment (eg, systemic analgesics, adjunctive therapies, IT morphine). The safety and efficacy of IT Prialt were evaluated in 3 double-blind, placebo-controlled, multicenter studies in 457 patients using 2 titration schedules; 4 additional open-label, long-term studies for chronic use of Prialt in 977 patients; and a randomized, double-blind, placebo-controlled study using IT Prialt in a slow titration in 220 patients with severe pain. In the latter study, Prialt dosing was started at 2.4 µg/d and the dose could be increased by 2.4 µg/d (2 to 3 times/wk) to a maximum dose of 19.2 µg/d. The primary efficacy variable was the mean percent change in Visual Analog Scale of Pain Intensity score from baseline to day 21. There was

a statistically significant difference in mean percent change in pain score with the Prialt-treated group ($n = 112$) as compared with the placebo-treated group ($n = 108$) at week 3 (12% versus 5%; $P = 0.04$). The most common adverse effects associated with Prialt were dizziness, nausea, confusion, headache, and somnolence. Patients with a history of psychosis should not be given Prialt. IT Prialt should be initiated at no more than 2.4 µg/d and titrated to patient response. Prialt can only be administered in the Medtronic SynchroMed EL or SynchroMed Infusion systems (Medtronic Inc., Minneapolis, MN) or the Simms Deltec Cadd Micro External Microinfusion Device and Catheter (Ardus Medical Inc, Cincinnati, OH).

VENTAVIS

CoTherix, Inc. (South San Francisco, CA) has been granted FDA approval to market Ventavis (iloprost) inhalation solution for the treatment of pulmonary arterial hypertension in patients with New York Heart Association (NYHA) class III or IV symptoms. Ventavis was evaluated in a randomized, double-blind, multicenter, placebo-controlled study in patients ($N = 203$) with NYHA class III or IV pulmonary arterial hypertension or pulmonary hypertension related to chronic thromboembolic disease. Patients received Ventavis 2.5 or 5.0 µg by repeated inhalations 6 to 9 times/d

during waking hours. The primary efficacy endpoint was clinical response at 12 weeks as defined by (1) improvement in exercise capacity (6-minute walk test) by at least 10% versus baseline 30 minutes after dosing, (2) improvement by at least 1 NYHA class versus baseline, and (3) no death or deterioration of pulmonary hypertension. Effectiveness of Ventavis was seen in the full study population; however, there was inadequate evidence of benefit in patients with pulmonary hypertension associated with chronic thromboembolic disease. The response rate for pulmonary arterial hypertension patients was 19% for the Ventavis group as compared with 4% for the placebo group. The most common adverse events reported with Ventavis were increased cough, headache, and vasodilation (flushing). Ventavis should be used with the Prodose AAD System (Promedic Inc., McCordsville, IN). The first inhaled dose should be 2.5 µg and, if tolerated, can be increased to 5.0 µg and maintained at that dose.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Tricia Faggioli, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.