

### Drugs recently approved or pending approval

#### ALOXI

The US Food and Drug Administration (FDA) has granted approval to MGI Pharma, of Minneapolis, MN, and to Helsinn Healthcare SA, of Lugano, Switzerland, to market Aloxi (palonosetron hydrochloride injection) for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy. Three multicenter, double-blind, phase III trials were conducted to compare the efficacy and safety of Aloxi with currently marketed 5HT<sub>3</sub> receptor antagonists. Study endpoints in each trial included complete response (defined as the percentage of patients that did not experience vomiting or use rescue medication) during the 0 to 24 hour, 24 to 120 hour, and 0 to 120 hour periods following chemotherapy. Aloxi was effective in prevention of both acute and delayed nausea. Overall (0–120 hours), Aloxi 0.25 mg was found efficacious in comparisons with ondansetron and dolasetron in patients with moderately emetogenic chemotherapy (69% with Aloxi versus 50% with ondansetron 32 mg [ $P < .001$ ] and 46% with Aloxi versus 34% with dolasetron 100 mg [ $P = .021$ ]). Approximately 1800 patients participated in the phase III clinical trials evaluating Aloxi, and the majority of patients were white women naïve to previous chemotherapy. Mean age was 55 years. The most common adverse effects associated with Aloxi were headache and constipation. The recommended dosage of Aloxi is 0.25 mg administered as a single dose 30 minutes prior to the start of chemotherapy.

#### BEXXAR

The FDA has granted approval to Corixa Corporation (Seattle, WA) and GlaxoSmithKline (Philadelphia, PA) to market Bexxar (tositumomab and iodine I-131 tositumomab) for the treatment of patients with CD20-positive, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to rituximab and has relapsed following chemotherapy. Bexxar was evaluated in a multicenter, single-arm study of patients with low-grade or transformed low-grade or follicular large-cell lymphoma whose disease had not responded to or had progressed after rituximab therapy. All patients ( $N = 40$ ) were required to have been previously treated with at least 4 doses of rituximab without an objective response or with progression following treatment and have a platelet count  $\geq 100,000/\text{mm}^3$ , an average of  $\leq 25\%$  of the intratrabeular

marrow space involved by lymphoma, and no evidence of progressive disease arising in a field irradiated with  $> 3500$  cGy within 1 year of completion of irradiation. Patients received thyroid-blocking agents and premedication to ameliorate or prevent infusion reactions. Median age was 57 years (range, 11–70 years) and the median number of prior chemotherapy regimens was 4 (range, 1–11). Overall, 35 of 40 (88%) patients met the definition of “rituximab refractory,” defined as no response or a response of less than 6 months duration. Overall response was 68% (95% confidence interval [CI], 51%–81%), and 33% of patients had a complete response (95% CI, 19%–49%). The median duration of follow-up was 26 months for all patients. The most common adverse effects reported with Bexxar include neutropenia, thrombocytopenia, and anemia that can be both prolonged and severe. Non-hematologic adverse effects include asthenia, fever, nausea, infection, and cough. Administration of Bexxar consists of 4 components given in 2 steps: the dosimetric step, followed 7 to 14 days later by a therapeutic step.



#### UROXATRAL

Sanofi-Synthelabo, Inc, of New York, NY, received approval from the FDA to market UroXatral (alfuzosin) for the treatment of the signs and symptoms of benign prostatic hyperplasia. The safety and efficacy of UroXatral was evaluated in 3 randomized, placebo-controlled, double-blind, parallel-arm, 12-week studies. Patients were randomized ( $N = 1608$ ), and 473 patients received UroXatral 10 mg daily. The primary efficacy variables in these trials were the International Prostate Symptom Score and peak urinary flow rate. The mean age of patients was 64 years (range, 49–92 years). There was a statistically significant reduction from baseline in all 3 studies ( $P = .001$ ,  $P = .002$ ,  $P = .007$ ), indicating a reduction in symptom severity. The most common adverse effects associated with UroXatral include dizziness, upper respiratory tract infection, headache, and fatigue. UroXatral should not be used in patients with moderate or severe hepatic insufficiency and should not be coadministered with potent CYP3A4 inhibitors because alfuzosin blood levels are increased with UroXatral usage. UroXatral tablets should not be chewed or crushed.

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

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