

In collaboration with the Food and Drug Administration (FDA), and as a service to our members, the Oncology Nursing Society will provide information about newly approved therapies for cancer patients. This will allow the FDA to inform ONS members of recent approvals in a timely manner. Included in this information from the FDA will be a link to the product label, which will provide the relevant clinical information on the indication, contraindications, dosing, and safety. In sending this information, ONS does not endorse any product or therapy and does not take any position on the safety or efficacy of the product or therapy described. The following is a message from the FDA's Office of Oncology Drug Products Director, Dr. Richard Pazdur:

On May 30, 2007, the U. S. Food and Drug Administration granted approval for temsirolimus (TORISEL™, Wyeth, Inc.) for the treatment of advanced renal cell carcinoma (RCC).

Efficacy and safety were demonstrated at a second interim analysis of a phase 3, multi-center, international, randomized, open-label study in previously untreated patients with advanced RCC who had 3 or more of 6 poor prognostic factors. These factors included time of diagnosis to randomization of less than one year, Karnofsky performance status of 60 or 70, hemoglobin less than the lower limit of normal, corrected calcium of greater than 10 mg/dL, lactate dehydrogenase > 1.5 times the upper limit of normal, and/or more than one metastatic organ site.

Six hundred and twenty six patients were randomized to one of three arms: Interferon alfa (IFN) alone (n=207), temsirolimus 25 mg alone (n=209), or the combination of temsirolimus 15 mg and IFN (n=210). Patients were stratified for prior nephrectomy and geographic region. Seventy percent were less than 65 years old and 69% were male. Temsirolimus was infused intravenously over 30-60 minutes once a week either until disease progression or unacceptable toxicity. Premedication with an antihistamine (e.g., diphenhydramine) was recommended.

Single-agent temsirolimus was associated with a statistically significant improvement in overall survival (OS) when compared to IFN (hazard ratio 0.73 [95% CI: 0.58, 0.92]; p= 0.0078. The median OS was 10.9 months on the temsirolimus arm and 7.3 months on the IFN arm. Progression-free survival (PFS) was a secondary endpoint and the median PFS was 5.5 months on the temsirolimus arm and 3.1 months on the IFN arm [hazard ratio 0.66 (95% CI: 0.53, 0.81)]. The combination of temsirolimus 15 mg and IFN did not result in a significant increase in OS when compared with IFN alone and was associated with an increase in multiple adverse reactions.

The most common adverse reactions (incidence ≥ 30%) were rash, asthenia, mucositis, nausea, edema, and anorexia. The most common laboratory abnormalities (incidence ≥30%) were anemia, hyperglycemia, hyperlipemia, hypertriglyceridemia, elevated alkaline phosphatase, elevated serum creatinine, lymphopenia, hypophosphatemia, thrombocytopenia, elevated AST, and leukopenia.

The most common grade 3/4 adverse reactions (incidence \geq 5%) included asthenia, dyspnea, rash, and pain. The most common grade 3/4 laboratory abnormalities (incidence \geq 5%) included hypertriglyceridemia, anemia, hypophosphatemia, hyperglycemia, lymphopenia, and neutropenia.

Rare serious adverse reactions associated with temsirolimus included interstitial lung disease, bowel perforation, and acute renal failure.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at www.fda.gov/cder/foi/label/2007/022088lbl.pdf.

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