

IN EVERY ISSUE

Kidney, Head and Neck Cancers & MDS

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Revlimid Reaches the Finish Line for Myelodysplastic Syndromes

After positive results in a phase III trial and a recommendation from the Food and Drug Administration's Oncology Drugs Advisory Committee, Revlimid (lenalidomide) was approved in late 2005 for certain types of myelodysplastic syndromes (MDS), a variety of blood disorders that can cause low blood counts, including anemia, which require frequent blood transfusions.

Revlimid is especially effective in a quarter of MDS patients who carry a specific chromosome 5 deletion. Taken orally, Revlimid can cause many of these patients to no longer need blood transfusions, improving their quality of life. A phase III trial showed Revlimid, a derivative of Thalomid (thalidomide), allowed two thirds of patients to become transfusion-independent for more than a year. Though no trial has shown a risk of birth defects in patients taking Revlimid, the drug is currently only available through a restricted distribution program called RevAssist, which requires doctors and pharmacists to register in order to prescribe the drug. Women must have regular pregnancy tests, and both men and women must use contraceptives.

In addition to MDS, Revlimid has also shown activity in patients with relapsed multiple myeloma. The FDA is considering the drug for multiple myeloma and is expected to approve Revlimid for that indication in mid-2006. It is also being tested in metastatic melanoma and chronic lymphocytic leukemia. Common side effects of Revlimid include neutropenia, fatigue and diarrhea.

For more information, visit www.revlimid.com

Double Approval for Sutent

The FDA approved a new oral drug called Sutent (sunitinib) in January for both advanced kidney cancer as well as a rare type of sarcoma of the stomach called gastrointestinal stromal tumor (GIST). The approval made Sutent the first drug to be simultaneously approved for two cancers.

Sutent blocks the activity of multiple enzymes (called tyrosine kinases) that are involved in transmitting signals from the outside to the inside of the cancer cell. Sutent can block the development of new blood vessels (called angiogenesis), essentially starving the tumor of blood and nutrients (see [“Picking Up Momentum for Treating Renal Cell Carcinoma.”](#)). In phase II trials, Sutent shrank tumors by at least a third in up to 37 percent of advanced kidney cancer patients.

GIST is a rare tumor that occurs in the stomach and other parts of the digestive system. Fortunately, most GIST patients respond to Gleevec (imatinib), but over time, some patients become resistant to Gleevec and need an alternative treatment. When used against Gleevec-resistant GIST, Sutent had significant activity, prolonging time to tumor progression from six weeks to 27 weeks when compared with placebo. The most commonly reported side effects include fatigue, diarrhea and a rash on the hands and feet.

For more information on Sutent, go to www.sutent.com.

Monoclonal Antibody Approval a First for Head & Neck Cancer

Erbix (cetuximab) received approval from the FDA on March 1 for head and neck cancer, a second approval for the monoclonal antibody, which is already on the market for treating metastatic colorectal cancer in combination with Camptosar (irinotecan). In 2005, nearly 40,000 Americans were diagnosed with head and neck cancer, including cancers of the tongue, mouth, salivary glands, throat and voice box.

In colorectal, head and neck and other cancers, the number of receptors for epidermal growth factors is higher on the surface of cancer cells than normal cells. When Erbitux binds to the epidermal growth factor receptor on cancer cells, it inhibits the signal for cancer cell growth. In one of the largest phase III studies ever conducted in head and neck cancer patients, Erbitux in combination with radiation prevented the spread of cancer more effectively than radiation alone and improved median survival by nearly two years.

Other studies show Erbitux is effective in patients whose cancers don't respond to platinum-based therapy, such as Paraplatin (carboplatin) and Platinol (cisplatin). The most common side effect with Erbitux is an acne-like rash.

For more information on Erbitux, go to www.erbitux.com.