

IN EVERY ISSUE

Colorectal Cancer, Lung Cancer & Lymphoma

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Vectibix Price Cap Follows Approval

In September, Vectibix® (panitumumab) joined Avastin® (bevacizumab) and Erbitux® (cetuximab) to become the third targeted agent approved for metastatic colorectal cancer and the first cancer drug to include a price cap for out-of-pocket patient expenses. Patients who spend more than 5 percent of their annual gross income on Vectibix will be enrolled in an assistance program that provides the drug for free. Colorectal cancer is the third most common cancer in the United States, with about 150,000 people diagnosed each year.

Vectibix targets the epidermal growth factor receptor, which is overexpressed in up to 77 percent of colorectal cancers and carries a bad prognosis and higher risk of metastasis. In a phase III trial of patients with metastatic colorectal cancer, Vectibix improved progression-free survival when compared with best supportive care (18 percent versus 5 percent). Three-quarters of the patients on best supportive care ultimately crossed over to the Vectibix arm, and nearly a third saw their disease stabilize.

At a cost of 20 percent less than Erbitux, its direct competitor, Vectibix was designed to lessen the risk of infusion reaction seen with Erbitux. In the trial, 1 percent of patients receiving Vectibix had an infusion reaction compared with 3 percent with Erbitux. And although rash was reported in 90 percent of Vectibix patients, the severity of the rash correlated with improved overall survival. Other common side effects of Vectibix include fatigue, pain, nausea and diarrhea.

Vectibix is administered by I.V. once every two weeks, and although it was approved for third-line therapy, a study is under way to test it as first-line therapy for metastatic colorectal cancer in combination with Avastin.

Researchers are also testing Vectibix in metastatic head and neck cancer, as first-line therapy for metastatic colorectal cancer and as adjuvant (after surgery) therapy for non-metastatic colorectal cancer. For more information, visit

Second Approval for Avastin

The Food and Drug Administration approved Avastin® (bevacizumab) in October as treatment for newly diagnosed patients with non-small cell lung cancer that either recurred or spread. More than 170,000 patients were diagnosed with lung cancer in 2006, most of them with non-small cell lung cancer. Genentech, Avastin's manufacturer, announced that it would establish a program to cap the annual cost of Avastin, an antiangiogenic therapy already approved for metastatic colorectal cancer, at \$55,000 for eligible patients. The cap applies to all approved indications.

Avastin essentially starves the tumor by stopping the growth of blood vessels that carry oxygen and nutrients to the tumor. When combined with carboplatin and Taxol® (paclitaxel), Avastin resulted in a 25 percent increase in overall survival compared with patients who received carboplatin and Taxol alone. Survival after one year also improved, with 51 percent of patients in the Avastin arm still alive compared with 44 percent for those not receiving the targeted agent. Median survival was also extended by 20 percent for the Avastin group, from 10.3 months to 12.3 months.

Common side effects of Avastin include diarrhea, nausea and vomiting and rash, with more severe side effects, such as hemorrhage and gastrointestinal perforation, occurring rarely. Avastin is currently in clinical trials for other cancers, including metastatic breast cancer, mesothelioma, kidney cancer and liver cancer. For more information on Avastin, visit www.avastin.com.

Drug for Rare Skin Lymphoma Given OK

Zolinza® (vorinostat) received approval from the FDA in October as a daily treatment of cutaneous T-cell lymphoma (CTCL), a rare form of non-Hodgkin's lymphoma that affects about 1,500 people a year. The two forms of CTCL, mycosis fungoides and Sezary syndrome, are characterized by a red skin rash that is often confused with psoriasis or eczema, but is in fact caused by malignant T cells that are drawn to the skin. The Zolinza approval is specifically for CTCL that has recurred or not responded to previous treatment.

Since CTCL specifically affects T cells, a type of white blood cell, Zolinza blocks cell growth and induces cell death in cancerous T cells. Zolinza may also obstruct several enzymes that inhibit the expression of genes that control normal cellular activity, thus allowing cells to regain normal functioning.

The approval was based on two clinical studies, including a phase II study that showed nearly 30 percent of patients responded to Zolinza. The study showed a period of six months may be needed before patients begin to see a response, but many of the participants in the trial who responded to Zolinza saw an improvement in less than eight weeks. The median time for cancer to progress in patients taking Zolinza was about five months. Common side effects include

fatigue, diarrhea and nausea.

Zolinza is undergoing testing for various types of leukemia, brain cancer and breast cancer. For more on Zolinza, visit www.zolinza.com.

Taxotere Approved for No. 7

Positive results of a phase III trial of Taxotere® (docetaxel) led the FDA to approve its use for locally advanced head and neck cancer in October. The study, which enrolled 358 patients, showed Taxotere in combination with cisplatin and 5-FU increased survival by more than four months (18.6 compared with 14.2 months).

After three years of follow-up, 62 percent of patients in the Taxotere arm were alive compared with 48 percent of patients in the cisplatin and 5-FU arm. Common side effects of the Taxotere-based combination included severe neutropenia (low white blood count), hair loss and anemia.

About 39,000 men and women were diagnosed with head and neck cancer in 2006 based on estimates from the National Cancer Institute. Head and neck cancer is a group of diseases that usually begin in cells that line the mouth, nose and throat, and accounts for up to 5 percent of all cancers in the United States.

The approval for head and neck cancer marks the seventh for Taxotere in the United States. Other indications for Taxotere include breast cancer, non-small cell lung cancer, prostate cancer and gastric (stomach) cancer. For more on Taxotere, visit www.taxotere.com.

Herceptin Expanded to Treat Early-Stage Breast Cancer

The FDA approved Herceptin® (trastuzumab) for its second indication in November after two large phase III studies revealed a 52 percent improvement in preventing recurrence when the monoclonal antibody was used after surgery (adjuvant) for HER2-positive early-stage breast cancer. In 1998, Herceptin was approved for HER2-positive metastatic breast cancer as a first-line therapy with Taxol and as a single agent for second- and third-line treatment.

Studies showed that Herceptin given for 52 weeks was added to the standard treatment of Adriamycin® (doxorubicin), Cytosan® (cyclophosphamide) and Taxol, the targeted agent succeeded in lowering the recurrence rate. Eighty-seven percent of women taking Herceptin were cancer-free after 3.5 years compared with 71 percent taking adjuvant chemotherapy alone. After a follow-up of only two years, researchers calculated that Herceptin also reduced the risk of dying from breast cancer by a third.

While nearly 213,000 cases of the disease will be diagnosed in the United States each year, only 25 percent of breast cancers overexpress HER2, a gene that is present in normal breast cells but overly abundant in some malignant cells. HER2-positive breast cancers are aggressive tumors that carry a poorer prognosis and higher risk of recurrence than HER2-negative tumors. Side effects of Herceptin include fever, nausea and rarely heart damage. For more on

Herceptin, visit www.herceptin.com.