FDA Approves New Drug Treatment for Type 2 Diabetes

The U.S. Food and Drug Administration today approved Onglyza (saxagliptin), a once-daily tablet to treat Type 2 diabetes in adults. The medication is intended to be used with diet and exercise to control high blood sugar levels.

The hormone insulin keeps blood sugar (glucose) levels within a narrow range in people who don't have diabetes. People with Type 2 diabetes are either resistant to insulin or do not produce enough insulin to maintain normal blood sugar levels.

Onglyza is in a class of drugs known as dipeptidyl peptidase-4 (DPP-4) inhibitors which stimulate the pancreas to make more insulin after eating a meal.

"Keeping blood sugar levels in adequate control is essential to the good health of the 24 million people in the United States with Type 2 diabetes," said Mary Parks, M.D., director of the Division of Metabolism and Endocrinology Products in the FDA's Center for Drug Evaluation and Research. "High blood sugar levels can cause blurry vision and excessive urination and eventually result in such serious conditions as kidney and eye disease."

The most common side effects observed with Onglyza are upper respiratory tract infection, urinary tract infection, and headache. Other side effects include allergic-like reactions such as rash and hives.

Approval of Onglyza was primarily based on the results of eight clinical trials. The application seeking FDA approval was submitted before December 2008 when the agency recommended that manufacturers of new diabetes drugs carefully design and evaluate their clinical trials for cardiovascular safety. Although Onglyza was not associated with an increased risk for cardiovascular events in patients who were mainly at low risk for these events, the FDA is requiring a postmarket study that will specifically evaluate cardiovascular safety in a higher risk population.

Onglyza is manufactured by Bristol-Myers Squibb Co. of Princeton, N.J., and marketed by Bristol-Myers and AstraZeneca Pharmaceuticals LP, of Wilmington, Del.

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FDA Approves First Maintenance Drug Therapy for Advanced Lung Cancer

The U.S. Food and Drug Administration has approved Alimta (pemetrexed), the first drug available for maintenance therapy of advanced or metastatic lung cancer.

Patients with cancer often receive maintenance therapy to prevent the disease from progressing after their tumor has shrunk or the disease has stabilized in response to chemotherapy. Alimta disrupts metabolic processes that are dependent on the B-vitamin folate, a necessary ingredient for cell replication.

"This drug represents a new approach in the treatment of advanced non-small cell lung cancer," said Richard Pazdur, M.D., director, Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research. "Typically, patients whose tumors respond to chemotherapy do not receive further treatment after four-to-six chemotherapy cycles. This study demonstrates an advantage in overall survival in certain patients who received Alimta for maintenance therapy."

Non-small cell lung cancer has several subtypes, including squamous cell, large cell, adenocarcinoma and mixed histology cancers. In a 600-patient clinical trial, people with predominantly squamous cell cancer did not benefit from Alimta. But those with other subtypes of non-small lung cancer survived an average 15.5 months following treatment compared with 10.3 months for patients who received an inactive substance (placebo). All patients in the study received standard medical care.

Reported adverse events included damage to blood cells, fatigue, nausea, loss of appetite, tingling or numbness in the hands and feet, and skin rash.

Alimta initially was approved in 2004 for the treatment of patients with mesothelioma, a cancer frequently related to asbestos exposure. The drug was later approved for the treatment of patients with non-small cell lung cancer whose disease worsened on prior chemotherapy drugs and also as an initial therapy for advanced non-small cell lung cancer.

Alimta is manufactured by Eli Lilly & Co. of Indianapolis.

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FDA Approves Multaq to Treat Heart Rhythm Disorder

The U.S. Food and Drug Administration has approved Multaq tablets (dronedarone) to help maintain normal heart rhythms in patients with a history of atrial fibrillation or atrial flutter (heart rhythm disorders). The drug is approved to be used in patients whose hearts have returned to normal rhythm or who will undergo drug or electric-shock treatment to restore a normal heart beat.

Multaq may cause critical adverse reactions, including death, in patients with recent severe heart failure. The drug's label will contain a boxed warning, the FDA's strongest warning, cautioning that the drug should not be used in severe heart failure patients.

"Multaq represents a therapeutic innovation for treatment of the heart rhythm disorder of atrial fibrillation," said Norman Stockbridge, M.D., Ph.D., director of the Division of Cardiovascular and Renal Products in the FDA's Center for Drug Evaluation and Research.

In a multinational clinical trial with more than 4,600 patients, Multaq reduced cardiovascular hospitalization or death from any cause by 24 percent, when compared with an inactive pill (placebo). Most of that effect represents reduced hospitalizations, especially hospitalizations related to atrial fibrillation. Atrial fibrillation and atrial flutter cause the heart to beat abnormally fast and sometimes prevent blood from being properly pumped out of the heart.

The most common adverse reactions reported by patients in clinical trials were diarrhea, nausea, vomiting, fatigue and loss of strength.

Multaq is manufactured by Paris-based sanofi-aventis.

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FDA Approves Drug for Treatment of Aggressive Brain Cancer

The U.S. Food and Drug Administration recently approved Avastin (bevacizumab) to treat patients with glioblastoma multiforme (GBM) when this form of brain cancer continues to progress following standard therapy.

GBM is a rapidly progressing cancer that invades brain tissue and can impact physical activities and mental abilities. It affects about 6,700 persons in the United States every year. Following initial treatment with surgery, radiation, and/or chemotherapy, the cancer nearly always returns.

"This type of cancer is very resistant to therapy and thus challenging to treat," said Richard Pazdur, M.D., director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research. "Avastin provides a therapy for patients with progressive GBM who have not responded to other medications."

Avastin is a laboratory-produced molecule known as a monoclonal antibody that mimics the antibodies produced by the body's immune system to defend against harmful substances. The medication inhibits the action of vascular endothelial growth factor that helps form new blood vessels. These vessels can feed a tumor, helping it to grow and can also provide a pathway for cancer cells to circulate in the body.

The drug was first approved in 2004 to treat metastatic cancer of the colon or rectum and has since been approved for treatment of non-squamous, non-small cell lung cancer and metastatic breast cancer.

In two clinical trials, about 25 percent of patients with GBM responded to Avastin with an average duration of response of about four months.

The most serious side effects associated with Avastin, in some cases resulting in death, are gastrointestinal perforation, wound healing complications, hemorrhage, and blood clots. Other serious side effects of Avastin are severe high blood pressure, nervous system and vision disturbances, decreased white blood cell counts, infection, stroke, myocardial infarction, and kidney problems.

The most common adverse reactions were nose bleeds, headache, high blood pressure, runny nose, excess proteins in the urine, taste alteration, dry skin, rectal bleeding, excessive tearing, and skin peeling.

Avastin is manufactured by Genentech Inc. of San Francisco.

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Source: FDA