Teriflunomide approved for relapsing multiple sclerosis

Sept. 12, 2012 The U.S. Food and Drug Administration today approved teriflunomide (Aubagio), a once-a-day tablet for the treatment of adults with relapsing forms of multiple sclerosis (MS).

MS is a chronic, inflammatory, autoimmune disease of the central nervous system that disrupts communication between the brain and other parts of the body. It is among the most common causes of neurological disability in young adults and occurs at least twice as frequently in women as in men. For most people with MS, episodes of relapses are initially followed by remissions. Over time, recovery periods may be incomplete, leading to progressive decline.

Teriflunomide is a pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of MS. The recommended dosage is 7 mg or 14 mg orally once daily, with or without food. The most common adverse reactions (>=10% and >=2% greater than placebo) are ALT increased, alopecia, diarrhea, influenza, nausea, and paresthesia.

The drug contains a Boxed Warning to alert prescribers and patients to the risk of severe liver injury including fatal liver failure, and a risk of birth defects. Physicians should check liver function before a patient starts taking teriflunomide and periodically during treatment. Teriflunomide is labeled as Pregnancy Category X, which means women of childbearing age must have a negative pregnancy test before starting the drug and use effective birth control during treatment. Nevertheless, teriflunomide may increase exposure of ethinylestradiol and levonorgestrel, and an appropriate oral contraceptive should been chosen.

FDA approves new orphan drug for chronic myelogenous leukemia

Sept. 4, 2012: The U.S. Food and Drug Administration today approved bosutinib (Bosulif) to treat chronic myelogenous leukemia (CML).

Bosutinib is a tyrosine kinase inhibitor. It inhibits the Bcr-Abl kinase that promotes CML. Bosutinib is indicated for the treatment of adult patients with chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy. Other drugs recently approved by FDA to treat various forms of CML include imatinib (2001), dasatinib (2006) and nilotinib (2007).

The safety and effectiveness of bosutinib was evaluated in a single clinical trial that enrolled 546 adult patients who had chronic, accelerated or blast phase CML. All patients had disease that progressed after treatment with imatinib or imatinib followed by dasatinib and/or nilotinib, or who could not tolerate the side effects of prior therapy. All patients in the trial were treated with bosutinib.

In patients with chronic phase CML, efficacy was determined by the number of patients who experienced a major cytogenetic response (MCyR) within the first 24 weeks of treatment. Results showed 34% of patients who had been previously treated with imatinib achieved MCyR after 24 weeks. Of the patients who achieved MCyR at any time, 52.8% had their response last at least 18 months. Among patients previously treated with imatinib followed by dasatinib and/or nilotinib, about 27% achieved MCyR within the first 24 weeks of treatment. Of those who achieved MCyR at any time, 51.4% had their MCyR last at least nine months.

In patients with accelerated CML previously treated with at least imatinib, 33% had their blood counts that returned to normal range (complete hematologic response) and 55% achieved normal blood counts with no evidence of leukemia (overall hematologic response) within the first 48 weeks of treatment. Meanwhile, 15% and 28% of patients with blast phase CML achieved complete hematologic response and overall hematologic response, respectively.

The recommended dose of bosutinib is 500 mg orally once daily with food. Most common adverse reactions (incidence greater than 20%) are diarrhea, nausea, thrombocytopenia, vomiting, abdominal pain, rash, anemia, pyrexia, and fatigue.

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