Biotech

FDA approves Gattex to treat short bowel syndrome

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FDA NEWS RELEASE**: FDA approves Gattex to treat short bowel syndrome**
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The U.S. Food and Drug Administration today approved Gattex (teduglutide) to treat adults with short

intestine. Extensive loss of the small intestine can lead to poor absorption of fluids and nutrients from food needed to sustain life. As a result, patients with SBS often receive parenteral nutrition.

Gattex is an injection administered once daily that helps improve intestinal absorption of fluids and nutrients, reducing the frequency and volume of parenteral nutrition. It is the third FDA-approved drug to treat adults with SBS receiving nutritional support. Zorbtive (somatropin) and Nutrestore (glutamine) were approved in 2003 and 2004, respectively.

"Today's approval expands the available treatment options for patients with this life-threatening condition," said Victoria Kusiak, M.D., deputy director of the Office of Drug Evaluation III in the FDA's Center for Drug Evaluation and Research. "Because Gattex may cause other serious health conditions, it is critical that patients and health care professionals understand the drug's potential and known safety risks."

Patients treated with Gattex have a potential increased risk of developing cancer and abnormal growths (polyps) in the intestine, obstructions in the intestine, gallbladder disease, biliary tract disease and pancreatic disease. To ensure that the benefits of Gattex outweigh the potential risks, the drug is being approved with a Risk Evaluation and Mitigation Strategy, consisting of a communication plan and training for prescribers.

Gattex's safety, efficacy and tolerability were evaluated in two clinical trials and two extension studies.

The clinical trials were designed to measure the number of patients who achieved at least 20 percent reduction in the volume of weekly parenteral nutrition after 20 and 24 weeks of treatment (clinical response). Forty-six percent and 63 percent of patients treated with Gattex achieved clinical response, versus 6 percent and 30 percent of patients treated with placebo.

The trials also measured the mean reduction in the volume of parenteral nutrition (liters per week) after 24 weeks of treatment. Results showed a mean reduction in parenteral nutrition of 2.5 L/week and 4.4 L/week in Gattex-treated patients, compared with 0.9 L/week and 2.3 L/week in placebo-treated patients.

The extension studies followed patients treated with Gattex in the clinical trials for an additional 28 weeks. Patients experienced a 4.9 L/week and 5.2 L/week mean reduction in parenteral nutrition after one year of continuous Gattex treatment. Six patients in the extension studies were weaned off parenteral nutrition while on Gattex.

The most common side effects of Gattex identified in clinical trials were abdominal pain, injection site reactions, nausea, headaches, abdominal distension and upper respiratory tract infection.

To study Gattex's long-term safety, the FDA is requiring a postmarket study of SBS patients treated with the drug in a routine clinical setting to further evaluate the drug's potential increased risk to cause colorectal cancer and other conditions. Patients in this study will be followed for at least 10 years.

Gattex is marketed by Bedminster, N.J.-based NPS Pharmaceuticals. Zorbtive is marketed by EMD Serono, based in Rockland, Mass. and Nutrestore is marketed by Torrance, Calif.-based Emmaus Medical Inc.

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