IMPORTANT DRUG WARNING
FDA-Required REMS Safety Information

Risks associated with GATTEX:

- Possible acceleration of neoplastic growth and enhancement of colon polyp growth
- GI obstruction
- Biliary and pancreatic disorders

Dear Healthcare Professional:

The purpose of this letter is to remind you about the serious risks associated with GATTEX® (teduglutide) for Injection and the need for ongoing monitoring for these risks.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of GATTEX outweigh the potential risks.

Serious Risks:

Acceleration of neoplastic growth and enhancement of colon polyp growth

- *Possible Acceleration of Neoplastic Growth*

Based on the pharmacologic activity and findings in animals, GATTEX has the potential to cause hyperplastic changes including neoplasia.

- *Possible Small Bowel Neoplasia*

Based on benign tumor findings in the mouse and rat carcinogenicity studies, patients should be monitored clinically for small bowel neoplasia. If a benign neoplasm is found, it should be removed. In case of small bowel cancer, GATTEX therapy should be discontinued.

- *Colorectal Polyps*

Colorectal polyps were identified during the clinical studies. In adults, colonoscopy of the entire colon with removal of polyps should be done within 6 months prior to starting treatment with GATTEX. A follow-up colonoscopy (or alternate imaging) is recommended at the end of 1 year of GATTEX. Subsequent colonoscopies should be done every 5 years or more often as needed. In children and adolescents, fecal occult blood testing should be performed prior to initiating treatment with GATTEX. Colonoscopy/sigmoidoscopy is required if there is unexplained blood in the stool. Perform subsequent fecal occult blood testing annually in children and adolescents while they are receiving GATTEX. Colonoscopy/sigmoidoscopy is recommended for all children and adolescents after 1 year of treatment, every 5 years thereafter while on continuous treatment with GATTEX, and if they have new or unexplained gastrointestinal bleeding.

Gastrointestinal obstruction

Intestinal obstruction has been reported in clinical studies. In patients who develop intestinal or stomal obstruction, GATTEX should be temporarily discontinued while the patient is clinically managed and restarted when the obstructive presentation resolves, if clinically indicated.

Biliary and pancreatic disorders

- *Gallbladder and Biliary Tract Disease*

Cholecystitis, cholangitis, and cholelithiasis, have been reported in clinical studies.
For identification of the onset or worsening of gallbladder/biliary disease, patients should undergo laboratory assessment of bilirubin and alkaline phosphatase within 6 months prior to starting GATTEX, and at least every 6 months while on GATTEX; or more frequently if needed.

- *Pancreatic Disease*

Pancreatitis has been reported in clinical studies. For identification of onset or worsening of pancreatic disease, patients should undergo laboratory assessment of lipase and amylase within 6 months prior to starting GATTEX, and at least every 6 months while on GATTEX; or more frequently if needed.

Appropriate Patient Selection, Counseling, and Monitoring

Prescribers should select the appropriate patients to receive GATTEX in accordance with the approved Prescribing Information (PI), discuss the benefits and risks of GATTEX with patients or caregivers, and monitor patients as specified in the approved (PI). The *Patient and Caregiver Counseling Guide* is available for use in discussing GATTEX with patients. The guide can be accessed via www.GATTEXREMS.com or by contacting 1-855-5GATTEX (1-855-542-8839).

GATTEX Healthcare Provider Training

As part of the REMS, healthcare providers who intend to prescribe GATTEX, should access www.GATTEXREMS.com to review the *Prescriber Education Slide Deck* and complete the *Post-Training Knowledge Assessment Questions*. Training can be completed either online or through a paper-based process:

1) **Online**: visit www.GATTEXREMS.com to review the REMS materials and follow the instructions to complete the Post-Training Knowledge Assessment Questions online.
2) **Paper-based**: review the REMS materials and fax the completed Post-Training Knowledge Assessment Questions to 1-855-359-3393.

Indication

GATTEX is indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Reporting Adverse Events

Report all suspected adverse events associated with the use of GATTEX, at 1-855-5GATTEX (1-855-542-8839); or to the FDA MedWatch program at 1-800-FDA-1088 (1-800-332-1088), or via the website at https://www.fda.gov/Safety/MedWatch/default.htm

Please see the enclosed PI for GATTEX for additional safety information.

Enclosures:

- *Prescriber Education Slide Deck*
- *Post-Training Knowledge Assessment Questions*
- *GATTEX Prescribing Information*
- *Medication Guide*