Gattex®
(teduglutide) for injection

You're Invited!

On behalf of **Linda Kiyokawa (Regional Business Manager)** and Takeda, please join us for the following virtual program:

- Provide an overview of Short Bowel Syndrome (SBS)
- Discuss the treatment goals for adult patients with SBS
- Understand the role of GATTEX (teduglutide) in SBS management
- Highlight considerations for initiating GATTEX as a treatment for appropriate patients

REGISTER NOW!

To register for this program, please call 1-855-575-3819 or register online at www.GIprograms.com/3070-97.

This program is open to healthcare professionals only. ***Please be advised that spouses and other guests are not permitted to participate.*** *Thank you in advance, and we look forward to your participation.*
This is not a CME program.

Who:
Mario Alcantara, MD
Colorectal Surgeon
South Texas Colorectal Center
San Antonio, TX

When:
Friday, February 5, 2021
11:45 AM PT

Where:
Virtual Webcast

Indication

GATTEX® (teduglutide) for injection 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.

IMPORTANT SAFETY INFORMATION

Warning and Precautions

Acceleration of Neoplastic growth

Colorectal polyps were identified during clinical trials. There is a risk for acceleration of neoplastic growth. In adults, within 6 months prior to starting treatment with GATTEX, colonoscopy of the entire colon with removal of polyps should be performed and follow-up colonoscopy (or alternate imaging) is recommended at the end of 1 year of GATTEX. Subsequent colonoscopies should be performed every 5 years or more often as needed.

In children and adolescents, perform fecal occult blood testing 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.

In case of intestinal malignancy (GI tract, hepatobiliary, pancreatic), discontinue GATTEX. The clinical decision to continue GATTEX in patients with non-gastrointestinal malignancy should be made based on benefit-risk considerations.

Please scroll for continued IMPORTANT SAFETY INFORMATION.

IMPORTANT SAFETY INFORMATION (continued)

Warning and Precautions (continued)

Intestinal obstruction

Intestinal obstruction has been reported in clinical trials and postmarketing. In patients who develop intestinal or stomal obstruction, GATTEX should be temporarily discontinued pending further clinical evaluation and management.

Biliary and pancreatic disease

Cholecystitis, cholangitis, cholelithiasis, and pancreatitis have been reported in clinical trials and postmarketing. Laboratory assessment (bilirubin, alkaline phosphatase, lipase, amylase) should be obtained within 6 months prior to starting GATTEX. Subsequent laboratory tests should be done every 6 months or more often as needed. If clinically meaningful changes are seen, further evaluation is recommended including imaging, and continued treatment with GATTEX should be reassessed.

Fluid imbalance and fluid overload

Fluid overload and congestive heart failure have been observed in clinical trials. If fluid overload occurs, especially in patients with underlying cardiovascular disease, parenteral support should be adjusted and GATTEX treatment reassessed. If significant cardiac deterioration develops while on GATTEX, continued GATTEX treatment should be reassessed.

Discontinuation of treatment with GATTEX may also result in fluid and electrolyte imbalance. Fluid and electrolyte status should be monitored in patients who discontinue treatment with GATTEX.

Increased absorption of concomitant oral medication

In clinical trials, one patient receiving prazepam concomitantly with GATTEX experienced dramatic deterioration in mental status progressing to coma during first week of GATTEX therapy. Patients receiving concomitant oral drugs requiring titration or with a narrow therapeutic index should be monitored for adverse reactions due to potential increased absorption of the concomitant drug. The concomitant drug may require a reduction in dosage.

Adverse Reactions

The most common adverse reactions (≥ 10%) with GATTEX are abdominal pain, nausea, upper respiratory tract infection, abdominal distension, injection site reaction, vomiting, fluid overload, and hypersensitivity.

Use in Specific Populations

Breastfeeding is not recommended during treatment with GATTEX.

Please click here for full Prescribing Information.

US-TED-0356v1.0 09/20

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Takeda