The critical role of glucagon-like peptide-2 (GLP-2) in intestinal function\textsuperscript{1-4}

**Indication**
GATTEX\textsuperscript{®} (Teduglutide [rDNA origin]) for Injection is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

**Warnings and Precautions**
GATTEX\textsuperscript{®} has been associated with possible acceleration of neoplastic growth and enhanced growth of colon polyps, gastrointestinal obstruction, gallbladder, biliary tract and pancreatic disease, increased absorption of fluids leading to fluid overload, and increased absorption of oral medications.

Please see additional Important Safety Information throughout this piece and click here for full Prescribing Information.
The action of endogenous GLP-2 plays a critical role in the absorption of nutrients in the intestine.\textsuperscript{1-5}

**Important Safety Information**

**Warnings and Precautions**

**Neoplastic growth**

Colorectal polyps were identified during clinical trials. There is a risk for acceleration of neoplastic growth. Colonoscopy of the entire colon with removal of polyps should be done within 6 months prior to starting treatment with GATTEX\textsuperscript{®} and is recommended after 1 year. Subsequent colonoscopies should be done as needed, but no less frequently than every 5 years. In case of intestinal malignancy (GI tract, hepatobiliary, pancreatic), discontinue GATTEX\textsuperscript{®}. The clinical decision to continue GATTEX\textsuperscript{®} in patients with non-gastrointestinal malignancy should be made based on risk and benefit considerations.

**Intestinal obstruction**

Intestinal obstruction has been reported in clinical trials. In patients who develop obstruction, GATTEX\textsuperscript{®} 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. Patients should undergo laboratory assessment (bilirubin, alkaline phosphatase, lipase, amylase) before starting GATTEX\textsuperscript{®}. Subsequent laboratory tests should be done every 6 months. If clinically meaningful changes are seen, further evaluation is recommended including imaging, and continued treatment with GATTEX\textsuperscript{®} should be reassessed.

*Please see additional Important Safety Information throughout this piece and click here for full Prescribing Information.*
GATTEX® is the first and only FDA-approved analog of naturally occurring human GLP-2™

**Important Safety Information**

**Warnings and Precautions (continued)**

**Fluid overload**

Fluid overload and congestive heart failure have been observed in clinical trials. There is potential for fluid overload while on GATTEX®. If fluid overload occurs, especially in patients with underlying cardiovascular disease, parenteral support should be appropriately adjusted and GATTEX® treatment reassessed.

**Increased absorption of concomitant oral medication**

Altered mental status in association with GATTEX® has been observed in patients on benzodiazepines in clinical trials. Patients on concomitant oral drugs (e.g., benzodiazepines, phenothiazines) requiring titration or with a narrow therapeutic index may require dose adjustment while on GATTEX®.

Please see additional Important Safety Information throughout this piece and click here for full Prescribing Information.
More than twice as many patients on GATTEX® had a response to treatment compared with placebo in STEPS\(^7,b\)

- 63% (27/43) of patients had at least a 20% reduction in weekly parenteral support\(^c\) volume from baseline (immediately before randomization) to both Weeks 20 and 24, versus 30% (13/43) of patients taking placebo (\(P=0.002\)) in the STEPS study\(^a\)

Patients sustained their response to GATTEX® in STEPS2\(^7,d\)

- 93% (28/30) of patients who received GATTEX® both in STEPS and STEPS2 for a total of 30 months had at least a 20% reduction in weekly parenteral support volume from baseline

- Of the responders in STEPS who had completed 2 additional years of continuous treatment with GATTEX®, 96% (21/22) sustained their response to GATTEX®

\(^a\)STEPS, a 6-month, randomized, double-blind, placebo-controlled, multicenter clinical trial of adult SBS patients dependent on parenteral support (PS) ≥3 times/week for ≥12 months, had, as a primary efficacy endpoint, a ≥20% reduction in weekly PS volume from baseline to Weeks 20 and 24.

\(^b\)Parenteral support refers to parenteral nutrition and/or essential fluids.

\(^c\)Subjects from STEPS (GATTEX®; n=37; placebo, n=39) enrolled in STEPS2, a 24-month, open-label extension study. All patients (N=88), including 12 who were never in STEPS, received GATTEX® in STEPS2. Results shown here use 30-month data only from subjects who received GATTEX® in STEPS and STEPS2. Response was defined as a ≥20% or greater reduction of weekly parenteral support.

\(^d\)More than twice as many patients on GATTEX® had a response to treatment compared with placebo in STEPS

### Important Safety Information

#### Adverse Reactions

The most common adverse reactions (≥10%) across all studies with GATTEX® are abdominal pain, injection site reactions, nausea, headache, abdominal distension, upper respiratory tract infection. In addition, vomiting and fluid overload were reported in the SBS studies (1 and 3) at rates ≥10%.

To report suspected adverse events, please contact Shire at 1-866-888-0660 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, contact Shire at 1-855-5GATTEX (542-8839), or visit www.gattex.com.

Please see additional Important Safety Information throughout this piece and click here for full Prescribing Information.

References: