# GATTEX KNOWS SBS



#### What is GATTEX?

GATTEX<sup>®</sup> (teduglutide) for subcutaneous injection is a prescription medicine used in adults and children 1 year of age and older with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support). It is not known if GATTEX is safe and effective in children under 1 year of age.

#### What is the most important information I should know about GATTEX?

**GATTEX may cause serious side effects including** making abnormal cells grow faster, polyps in the intestines, blockage of the bowel (intestines), swelling (inflammation) or blockage of your gallbladder or pancreas, and fluid overload.



Please see additional Important Safety Information throughout and click for full <u>GATTEX Prescribing Information</u>.





This brochure is designed for you. We know that to get here, you have overcome many challenges. You are on PS, and you want to know how GATTEX can help manage your short bowel syndrome with intestinal failure (SBS-IF). Throughout you will find **data, personal testimonials from** real patients, and resources for you. Persistence is key, so we've also included information to help keep you motivated. We're here to support you, because GATTEX knows SBS.



\*New patients from February 2013 through March 2023 for all approved indications.

#### **IMPORTANT SAFETY INFORMATION**

#### Making abnormal cells grow faster

GATTEX can make abnormal cells that are already in your body grow faster. There is an increased risk that abnormal cells could become cancer. If you get cancer of the bowel (intestines), liver, gallbladder or pancreas while using GATTEX, your healthcare provider should stop GATTEX. If you get other types of cancers, you and your healthcare provider should discuss the risks and benefits of using GATTEX.

#### Polyps in the intestines

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Polyps are growths on the inside of the intestines. For adult patients, your healthcare provider will have your colon and upper intestines checked for polyps within 6 months before starting GATTEX, and have any polyps removed. To keep using GATTEX, your healthcare provider should have your colon and upper intestines checked for polyps at the end of 1 year of using GATTEX.



### **About SBS and Its Management**

SBS is a serious and chronic malabsorption disorder. It is the result of the physical loss of some intestine leading to a diminished ability to absorb nutrition (functional deficiency), primarily due to surgical resection.

#### Some important treatment goals



Lowering or eliminating the need for long-term PS and reducing complications over time



Helping the intestine adapt



Maintaining healthy levels of nutrition and hydration



#### What to ask about

Different people need different care. It's important to work with your doctor to set your treatment goals.

Scan or <u>click here</u> to learn more about SBS management

### **Parenteral Support**

PS can provide fluids and/or nutrition. Depending on need, there are two types of PS:

- Intravenous (IV) fluids deliver necessary hydration along with a mix of electrolytes through a vein
- Total parenteral nutrition (TPN) can include a mix of proteins, carbohydrates, fats, vitamins, and minerals delivered through a central or peripheral line

PS does not increase intestinal absorption of essential nutrients.

Although PS is a life-saving intervention, long-term use of PS has been linked to kidney and liver issues as well as other health complications. It's important to discuss long-term treatment expectations and impacts with your healthcare provider.

### **Reducing Volume of PS**

**Clinically proven:** at **6 months**, 63% of adults reduced their PS volume. At **30 months**, 93% reduced their PS volume.



#### GATTEX was evaluated in 2 trials, STEPS (Study 1) and STEPS-2 (Study 2):



**STEPS: In this 6-month study of 86 adults** (aged 18 and over) with SBS who needed PS, 43 received GATTEX and 43 received placebo. The study's main goal was to evaluate the ability of GATTEX to reduce patients' weekly PS volume by at least 20% from baseline to both Weeks 20 and 24. The study also evaluated the average reduction of weekly PS volume from baseline, the number of people who reduced PS administration by at least 1 day per week, and safety.



**STEPS-2: In this 24-month study of 88 adults** (aged 18 and over) with SBS who needed PS, 76 had participated in STEPS (Study 1). The study's main goal was to evaluate the average reduction of weekly PS volume since the beginning of the study. The study also looked at the percentage of people who achieved at least a 20% reduction in weekly PS volume, the number of people who reduced their PS administration by at least 3 days per week, the number of people who completely stopped PS, and safety.

#### IMPORTANT SAFETY INFORMATION (Cont'd)

#### Polyps in the intestines (Cont'd)

For pediatric patients, your healthcare provider will check for blood in the stool within 6 months before starting GATTEX. If there is blood in the stool, your healthcare provider will check your colon and upper intestines for polyps, and have any polyps removed. To keep using GATTEX, your healthcare provider will check for blood in the stool every year during treatment of GATTEX. If there is blood in the stool, your healthcare provider will check your colon and upper intestines for polyps. The colon will be checked for polyps at the end of 1 year of using GATTEX.

For adult and pediatric patients, if no polyp is found at the end of 1 year, your healthcare provider should check you for polyps as needed and at least every 5 years. If any new polyps are found, your healthcare provider will have them removed and may recommend additional monitoring. If cancer is found in a polyp, your healthcare provider should stop GATTEX.



### **Reducing Time on PS**

Clinically proven: at 30 months, adults were able to have **3 or more days** off PS per week.





After starting GATTEX, I was able to reduce my PS volume and time from 7 days to 5 days. This time off PS gave me freedom to do more activities with my family.

MARRIKA - Treating her SBS with GATTEX. Individual results may vary.

#### IMPORTANT SAFETY INFORMATION (Cont'd)

#### Blockage of the bowel (intestines)

A bowel blockage keeps food, fluids, and gas from moving through the bowels in the normal way. Tell your healthcare provider right away if you have any of these symptoms of a bowel or stomal blockage:

- trouble having a bowel movement or passing gas
- nausea vomiting
- stomach area (abdomen) pain or swelling
- swelling and blockage of your stoma opening, if you have a stoma

If a blockage is found, your healthcare provider may temporarily stop GATTEX.



### **Weaning Off PS**

For appropriate patients, weaning off PS is an important, long-term goal. It is possible for some patients, but it is helpful to understand the **average time** it took to wean off PS was approximately **20 months** for patients in GATTEX clinical studies (~7 months to 30 months). Talk to your doctor about your long-term and short-term goals for reducing PS and how GATTEX may help.



#### GATTEX can eliminate the need for PS, for some people

Yes, it's possible. Every patient has different circumstances, intestines, abilities to absorb nutrients, and response times.



#### ~7 months<sup>†</sup>

~30 months<sup>†</sup>

Some people were able to fully wean off of PS after 7 months of treatment with GATTEX. Some people needed up to 30 months of treatment with GATTEX to fully wean off of PS.

88 people in STEPS-2 study received GATTEX, including 30 who received GATTEX for 30 months. Not everyone who takes GATTEX will fully wean off of PS. No one receiving GATTEX during the 6-month STEPS study achieved PS independence.

\*In STEPS-2, participants continued on GATTEX even if they no longer required PS. †Average at approximately 20 months.

#### IMPORTANT SAFETY INFORMATION (Cont'd)

#### Swelling (inflammation) or blockage of your gallbladder or pancreas

Your healthcare provider will do tests to check your gallbladder and pancreas within 6 months before starting GATTEX and at least every 6 months while you are using GATTEX. Tell your healthcare provider right away if you get:

 stomach area (abdomen) pain and tenderness

chills

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- fever
- a change in your stools
- nausea

- vomitingdark urine
- yellowing of your skin or the whites of your eyes



### **GATTEX Side Effects**

GATTEX may cause side effects. If you have any questions about side effects, whether before or during treatment, discuss with your healthcare provider.

Below are the **most common side effects<sup>‡</sup> (≥10%)** in 2 clinical studies of adult patients with SBS.

Side Effect	GATTEX (77 people)	Placebo (59 people)
Stomach area pain <sup>1</sup>	30%	22%
Nausea	23%	20%
Upper respiratory tract infection <sup>2</sup>	21%	12%
Stomach area swelling	20%	2%
Skin reaction where injection was given <sup>3</sup>	13%	12%
Vomiting	12%	10%
Swelling of the hands or feet <sup>4</sup>	12%	7%
Allergic reactions <sup>5</sup>	10%	7%

<sup>‡</sup> Reported at a rate of at least 10% and greater than the placebo group.

<sup>1</sup>Includes: Abdominal pain, upper abdominal pain, lower abdominal pain.

- <sup>2</sup>Includes: Upper respiratory tract infection, nasopharyngitis, pharyngitis, sinusitis, laryngitis, rhinitis, viral upper respiratory tract infection.
- <sup>3</sup>Includes: Injection site hematoma, injection site erythema, injection site pain, injection site swelling, injection site hemorrhage, injection site discoloration, injection site reaction, injection site rash.

<sup>4</sup>Includes: Fluid overload, peripheral edema, edema, generalized edema, fluid retention and jugular vein distension. <sup>5</sup>Includes: Erythema, rash, dermatitis allergic, pruritus, rash macular, drug eruption, eyelid edema, flushing.

GATTEX may cause serious side effects, including making abnormal cells grow faster, polyps in the colon (large intestine), blockage of the bowel (intestines), swelling (inflammation) or blockage of the gallbladder or pancreas, and fluid overload (too much fluid in your body).

### If you experience any side effects, check in with your doctor. Continue taking GATTEX as long as your doctor recommends, and work together to understand treatment expectations.

#### IMPORTANT SAFETY INFORMATION (Cont'd)

#### Fluid overload

Your healthcare provider will check you for too much fluid in your body. Too much fluid in your body may lead to heart failure, especially if you have heart problems. Tell your healthcare provider if you get swelling in your feet and ankles, you gain weight very guickly (water weight), or you have trouble breathing.



### **Taking GATTEX**

GATTEX is a self-administered once-daily injection under the skin (subcutaneous).



Inject **once daily** at the same time



stomach area, either thigh, or either upper arm





See a step-by-step administration video

Scan or <u>click here</u> to watch video

- GATTEX comes as a powder for injection in a vial that is used only 1 time (single-use vial)
- The powder must be mixed with sterile water for injection (a diluent) provided in a prefilled syringe before you inject it
- GATTEX must be injected within 3 hours after you mix it with the diluent

#### Before you start GATTEX, you must receive administration training by a healthcare professional.

**These are not all the steps**, just a general guide. Be sure to refer to the full Instructions for Use in the pocket about how to prepare and inject a dose of GATTEX.



Finding something that works for you might take time and effort, but in the end, it's worth it.

**PEGGY -** Treating her SBS with GATTEX. Individual results may vary.

#### IMPORTANT SAFETY INFORMATION (Cont'd) The most common side effects of GATTEX in adults include:

- stomach area (abdomen) pain or swelling
- nausea
- cold or flu symptoms
- skin reaction where the injection was given

Gattex (teduglutide) for injection

Please see additional Important Safety Information throughout and click for full <u>GATTEX Prescribing Information</u>.

### **Understanding the Importance of GLP-2**

GATTEX works like GLP-2 (glucagon-like peptide 2), a naturally occurring hormone in the body that increases villi height.

#### What are Villi? (in the intestine)



#### GATTEX increases the absorption of nutrients within the intestine

\*The ability of GATTEX to improve the amount of fluid absorbed by the intestines was studied in 17 adult subjects with SBS. Participants in the study received GATTEX for 21 days. All the participants in this study knew they were taking GATTEX. They each took daily doses of either 0.03, 0.10, or 0.15 mg/kg by subcutaneous injection (0.6 to 3 times the recommended dose). The recommended dose is 0.05 mg/kg/day. The injections were administered under the skin in the stomach area (abdomen). All of the doses studied, except for the 0.03 mg/kg once-daily dose, resulted in enhanced absorption of fluid by the intestines—approximately 750 to 1,000 mL per day—and increased the surface area of the intestines.

#### IMPORTANT SAFETY INFORMATION (Cont'd) The most common side effects of GATTEX in adults include (Cont'd):

- vomiting
- swelling of the hands or feet
- allergic reactions

The side effects of GATTEX in children and adolescents are similar to those seen in adults. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.



### **Know What to Expect**

#### Talk to someone about GATTEX

Connect directly with adults living with short bowel syndrome who know what it's like to be dependent on parenteral support and take GATTEX.



**Hear from a GATTEX patient** Meet Misa, a passionate SBS advocate, mom, and animal lover.



Scan or <u>click here</u> to watch video

### **SBSconnect**

When you speak with an SBS Mentor, you'll hear from an adult who understands SBS and being dependent on PS. Connect with an SBS Mentor and share relatable experiences and stories. Plus, hear about their own personal experiences with GATTEX.

Scan or <u>click here</u> to learn more or visit <u>gattex.com/sbs-connect</u>

This program is not intended for the purpose of disease diagnosis, to provide medical advice, or as a substitute for information that is provided to you by your physician. You should always discuss your medical condition and any questions you have with your physician.

This is a program where adults with short bowel syndrome, who are dependent on parenteral support, and caregivers can speak to a mentor with SBS over the phone.

#### IMPORTANT SAFETY INFORMATION (Cont'd) What should I tell my healthcare provider before using GATTEX?

#### Tell your healthcare provider about all your medical conditions, including if you or your child:

- have cancer or a history of cancer
- have or had polyps anywhere in your bowel (intestines) or rectum
- have heart problems
- have high blood pressure
- have problems with your gallbladder, pancreas, kidneys
- are pregnant or planning to become pregnant. It is not known if GATTEX will harm your unborn baby. Tell your

healthcare provider right away if you become pregnant while using GATTEX.

• are breastfeeding or plan to breastfeed. It is not known if GATTEX passes into your breast milk. You should not breastfeed during treatment with GATTEX. Talk to your healthcare provider about the best way to feed your baby while using GATTEX.



### **Resources for You**

<image>

After starting treatment with GATTEX, I was able to eventually wean completely off PS. I like having my freedom from PS.\*

**DENISE -** Treating her SBS with GATTEX. Individual results may vary.



\*In a 6-month study, 27 out of 43 adults treated with GATTEX reduced weekly PS volume by 20% or more versus 13 out of 43 on placebo. In a 24-month extension study, 10 out of 30 adults previously on GATTEX no longer needed PS after 30 months of treatment.

#### IMPORTANT SAFETY INFORMATION (Cont'd) What should I tell my healthcare provider before using GATTEX? (Cont'd)

**Tell your healthcare providers about all the medicines you take**, including prescription or over-the-counter medicines, vitamins, and herbal supplements. Using GATTEX with certain other medicines may affect each other causing side effects. Your other healthcare providers may need to change the dose of any oral medicines (medicines taken by mouth) you take while using GATTEX. Tell the healthcare provider who gives you GATTEX if you will be taking a new oral medicine.



Please see additional Important Safety Information throughout and click for full <u>GATTEX Prescribing Information</u>.

### **Additional Resources**

These are nonprofit organizations that support patients with SBS, like you.\*



\*This information is provided as a resource and not intended to be an endorsement. Takeda is not responsible for the content of any website not owned by Takeda.

#### IMPORTANT SAFETY INFORMATION (Cont'd) What should I tell my healthcare provider before using GATTEX? (Cont'd)

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.



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### Connect With Specialists You Can Count On

When you're prescribed GATTEX, Takeda Patient Support is here for you. Shortly after enrolling, you'll receive a call from us to welcome you to the program. We'll let you know what to expect and explain how we can assist you. We're here to address your questions and concerns and help get you the answers, resources, and tools you need.

#### WE CAN ALSO:



Enroll you in the Takeda Patient Support Co-Pay Assistance Program, if you qualify<sup>†</sup>



Arrange for nursing support if you have questions about your condition and your prescribed GATTEX treatment



Provide you with tips and timely information throughout your GATTEX treatment





Direct you to community support resources and education

Help you receive your treatment when you need it



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#### **NEED ASSISTANCE?**

Our support specialists are never more than a tap or a call away— **1-866-888-0660**, **Monday through Friday, [8:30** AM **to 8** PM **ET].** 

Not enrolled? You can join Takeda Patient Support in a few simple steps at <u>TakedaPatientSupport.com/enroll</u>. If English is not your preferred language, let us know. We may be able to assist you in the language of your choosing.

<sup>†</sup>To be eligible, you must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Call us for more details.



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#### IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about GATTEX?

#### GATTEX may cause serious side effects, including:

#### Making abnormal cells grow faster

GATTEX can make abnormal cells that are already in your body grow faster. There is an increased risk that abnormal cells could become cancer. If you get cancer of the bowel (intestines), liver, gallbladder or pancreas while using GATTEX, your healthcare provider should stop GATTEX. If you get other types of cancers, you and your healthcare provider should discuss the risks and benefits of using GATTEX.

#### Polyps in the intestines

Polyps are growths on the inside of the intestines. For adult patients, your healthcare provider will have your colon and upper intestines checked for polyps within 6 months before starting GATTEX, and have any polyps removed. To keep using GATTEX, your healthcare provider should have your colon and upper intestines checked for polyps at the end of 1 year of using GATTEX.

For pediatric patients, your healthcare provider will check for blood in the stool within 6 months before starting GATTEX. If there is blood in the stool, your healthcare provider will check your colon and upper intestines for polyps, and have any polyps removed. To keep using GATTEX, your healthcare provider will check for blood in the stool every year during treatment of GATTEX. If there is blood in the stool, your healthcare provider will check your colon and upper intestines for polyps. The colon will be checked for polyps at the end of 1 year of using GATTEX.

For adult and pediatric patients, if no polyp is found at the end of 1 year, your healthcare provider should check you for polyps as needed and at least every 5 years. If any new polyps are found, your healthcare provider will have them removed and may recommend additional monitoring. If cancer is found in a polyp, your healthcare provider should stop GATTEX.

#### Blockage of the bowel (intestines)

A bowel blockage keeps food, fluids, and gas from moving through the bowels in the normal way. Tell your healthcare provider right away if you have any of these symptoms of a bowel or stomal blockage:

- trouble having a bowel movement or passing gas
- stomach area (abdomen) pain or swelling
- vomiting

• swelling and blockage of your stoma opening, if you have a stoma

nausea

If a blockage is found, your healthcare provider may temporarily stop GATTEX.

#### Swelling (inflammation) or blockage of your gallbladder or pancreas

Your healthcare provider will do tests to check your gallbladder and pancreas within 6 months before starting GATTEX and at least every 6 months while you are using GATTEX. Tell your healthcare provider right away if you get:

- stomach area (abdomen) pain and tenderness
- chills
- fever

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• a change in your stools

- nausea
- vomiting
- dark urine
- · yellowing of your skin or the whites of your eyes



### IMPORTANT SAFETY INFORMATION (Cont'd)

#### Fluid overload

Your healthcare provider will check you for too much fluid in your body. Too much fluid in your body may lead to heart failure, especially if you have heart problems. Tell your healthcare provider if you get swelling in your feet and ankles, you gain weight very quickly (water weight), or you have trouble breathing.

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- cold or flu symptoms skin reaction where the injection was given
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- have high blood pressure
- have problems with your gallbladder, pancreas, kidneys
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Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

## For additional safety information, click here for full <u>Prescribing Information</u> and <u>Medication Guide</u>, and discuss any questions with your doctor.



### **Reduce Parenteral Support with GATTEX**

In clinical studies, GATTEX was proven to help people with SBS on PS



\*In a 6-month study, 27 out of 43 adults treated with GATTEX reduced weekly PS volume by 20% or more versus 13 out of 43 on placebo, and 21 out of 39 achieved at least 1 day off PS per week versus 9 out of 39 on placebo. After 30 months of treatment, 10 out of 30 adults no longer needed PS.

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OR SCAN/CLICK



With nearly 30 years of experience in gastroenterology, Takeda continues its commitment to GI patients

