Dec 21, 2012

FDA Approves Gattex® (teduglutide [rDNA Origin]) for Injection for the Treatment of Adult Short Bowel Syndrome

-- First major long-term treatment advance for adult SBS in nearly 40 years --
-- U.S. launch in first quarter of 2013 --
-- NPS Pharmaceuticals to host conference call on January 2, 2013 at 5:00 PM ET --

BEDMINSTER, N.J., Dec. 21, 2012 /PRNewswire/ -- NPS Pharmaceuticals, Inc. (NASDAQ: NPSP), a biopharmaceutical company pioneering and delivering therapies that transform the lives of patients with rare diseases worldwide, today announced that the U.S. Food and Drug Administration (FDA) has approved Gattex® (Teduglutide [rDNA origin]) for Injection, for subcutaneous use for the treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support. Gattex will be available in the first quarter of 2013. For full prescribing information, please visit www.Gattex.com.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/mnr/59518-nps-pharmaceuticals-fda-approval-gattex-adult-short-bowel-syndrome-sbs

"Gattex is a ground-breaking therapy that has been evaluated in the largest clinical program to date in short bowel syndrome," said Francois

Nader, MD, president and chief executive officer of NPS Pharmaceuticals. "We are very excited about the opportunity to help SBS patients by offering this first-in-class therapy. The approval of Gattex is a crowning achievement for our company and the catalyst for our transformation into a premier orphan drug business. We are prepared for a successful launch based on productive interactions with payers, methodical patient identification, and the strategic development of our field-based commercial infrastructure. We have also launched NPS Advantage, our free support program that includes, care coordinators who will work closely with patients to help them understand the clinical characteristics of Gattex and navigate the reimbursement landscape."

SBS is a serious, complex disorder in which the body is unable to absorb enough nutrients and fluids through the gastrointestinal tract to sustain life. SBS patients are commonly infused with PN/IV five to seven nights per week for up to 10 to 12 hours at a time, and in extreme cases, some patients could receive PN/IV for 24 hours a day. Long-term use of PN/ IV fluids can be associated with life-threatening complications such as liver damage, serious bloodstream infections, and blood clots.

Gattex is the first major long-term treatment advance for SBS in nearly 40 years. The unique mechanism of action of Gattex enhances gastrointestinal absorption. In Phase 3 studies, significant reductions in PN/IV volume and infusion days per week were achieved from pre-treatment baseline. In addition, some patients achieved independence from PN/IV support.

"In addition to serious medical complications, patients with short bowel syndrome can have socially-restricted lives. Long infusion periods often disrupt sleep for patients. This is coupled with constant concern about using restrooms as many patients will need to use the bathroom up to 25 times a day or having an accident with unpredictable diarrhea. Other patients that have an ostomy bag have a fear of an ostomy bag leakage. These factors leave many patients unable to socialize or work," said Ken Fujioka, MD, Nutrition and Metabolic Research Center, Scripps Clinic, Del Mar. "Considering Gattex has been shown to significantly reduce or in some cases even eliminate the requirement for parenteral support, it may become a cornerstone therapy in the management of short bowel syndrome."

SBS typically occurs when a large portion of the intestine has been removed by surgery caused by disease or injury. In rare cases, it is congenital. Common symptoms of SBS can include diarrhea, dehydration, malnutrition, and weight loss, which are closely related to the functional issues of the bowel. During a typical day, SBS patients will move their bowels up to 10 times, or change their ostomy bag, which collects their urine output, three to four times. In extreme cases, patients may move their bowels as many as 25 times each day.

"Patients with short bowel syndrome/intestinal failure need a comprehensive program to receive optimal care so that their quality of life is maintained to its fullest extent. The Oley Foundation encourages research and new development of drugs, products and services that improve health and well-being," said Joan Bishop, executive director, The Oley Foundation. "We are pleased that NPS Pharmaceuticals has engaged in this research and has set upon a path that serves to bring hope that it will reduce the challenges of short bowel syndrome/intestinal failure and improve the quality of life of many of our members and their families."

NPS Advantage™

To assist patients and healthcare professionals in facilitating care with Gattex, NPS has launched a free support program called NPS Advantage™. This program is designed to help navigate all aspects of care, help with insurance authorizations and appeals, answer questions about Gattex and its use, and locate resources for patients that connect them to care.

A key feature of NPS Advantage is the involvement of experienced care coordinators, who provide comprehensive support with a single point of contact. These NPS professionals will work with Gattex patients to confirm authorizations and benefit approvals for Gattex and help resolve health insurance issues. They will also support healthcare professionals to streamline the reimbursement process for Gattex and help their patients obtain appropriate medical care. For more information, please visit http://www.npsadvantage.com.

Conference Call Information

NPS will host a conference call to discuss its commercialization plan for Gattex, including the cost of therapy, on Wednesday, January 2, 2013 at 5:00 p.m. Eastern Time. To participate in the conference call, dial (800) 706-7748 and use pass code 18085144. International callers may dial (617) 614-3473, using the same pass code. In addition, a live audio of the conference call will be available over the Internet. Interested parties can access the event through the NPS website, http://www.npsp.com.

For those unable to participate in the live call, a replay will be available at (888) 286-8010, with pass code 79197503, until midnight Eastern Time, January 16, 2013. International callers may access the replay by dialing (617) 801-6888, using the same pass code. The webcast will also be available through the NPS website for the same period.

About Short Bowel Syndrome

Short bowel syndrome (SBS) is a highly disabling condition that can impair a patient's quality of life and lead to serious life-threatening complications. SBS typically arises after extensive resection of the bowel due to Crohn's disease, ischemia or other conditions. SBS patients often suffer from malnutrition, severe diarrhea, dehydration, fatigue, osteopenia, and weight loss due to the reduced intestinal capacity to absorb nutrients, water and electrolytes. The usual treatment for SBS is nutritional support, including parenteral nutrition (PN) and/or intravenous (IV) fluids to supplement and stabilize nutritional needs.

Although PN can provide nutritional support for SBS patients, it does not improve the body's own ability to absorb nutrients. PN is associated with serious complications, such as infections, blood clots or liver damage, and the risks increase the longer patients are on PN. Patients on PN often experience poor quality of life with difficulty sleeping, and frequent urination, and patients receiving chronic PN often experience a loss of independence.

Gattex Clinical Trials

NPS' clinical development program for Gattex is the largest and most comprehensive conducted in SBS patients to date, consisting of 15 clinical studies. Across all clinical studies, 566 subjects were exposed to at least one dose of Gattex, of whom 134 had SBS and were treated with 0.05 mg/kg/day Gattex. The FDA's approval of Gattex was based on an international, 24-week, double-blind, placebo-controlled, pivotal Phase 3 trial, known as STEPS. The primary endpoint of STEPS was defined as a 20 percent or greater PN/IV volume reduction demonstrated at week 20 and sustained at week 24. The study's secondary endpoints included reductions in PN/IV volume and additional days off therapy. Key findings from the STEPS trial include:

- In an intent-to-treat analysis at weeks 20 and 24, 63 percent of patients treated with Gattex achieved at least a 20 percent reduction in weekly PN/IV volume when compared to baseline, versus 30 percent for placebo ($p=0.002$).
- After 24 weeks of treatment, PN volume declined by 32 percent (4.4 L/wk) in Gattex-treated patients, versus 21 percent (2.3 L/wk) in the placebo group ($p<0.001$).
- After 24 weeks of treatment, 54 percent of Gattex-treated patients were able to reduce the number of infusion days per week by one or more days, compared to 23 percent of those treated with placebo ($p=0.005$).

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

For full prescribing information, please visit www.Gattex.com.

About Gattex® (teduglutide [rDNA origin]) for Injection

Gattex® (teduglutide [rDNA origin]) for Injection, for subcutaneous use is a novel, recombinant analog of human glucagon-like peptide 2, a

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