Gattex Gains Approval in SBS; NPS Plans 1Q Launch

By Jennifer Boggs
Managing Editor

NPS Pharmaceuticals Inc. won't have to wait until after the Christmas holidays after all. The FDA gave its nod Friday to Gattex (teduglutide [rDNA origin]) as the first long-term treatment for short bowel syndrome (SBS) in 40 years.

The approval, which came nine days ahead of the PDUFA date – the original Sept. 30 PDUFA date had been extended for three months to give reviewers additional time – had been largely expected, given the favorable briefing documents released followed by the unanimous recommendation by the FDA's Gastrointestinal Drugs Advisory Committee in October. (See *BioWorld Today*, Oct. 17, 2012.)

Gattex is a recombinant analogue of glucagon-like peptide 2, a peptide involved in normal intestinal function and fluid and nutrient absorption. It works by enhancing that fluid and nutrient absorption in patients with SBS, who are unable to absorb sufficient nutrients and fluids in their gastrointestinal tracts and usually end up relying on frequent parenteral nutrition and/or intravenous fluids (PN/I.V.). Those PN/I.V. infusions can occur five to seven nights per week for up to 10 to 12 hours at a time, with extreme cases requiring 24-hour PN/I.V.

An orphan indication, SBS is estimated to affect about 10,000 to 15,000 in the U.S. It is typically caused by extensive resection of the bowel.

In Phase III testing, Gattex produced significant reductions in PN/I.V. volume and infusion days per week, compared to pre-treatment baseline, with some patients actually able to achieve PN/I.V. independence. Initial results showed a benefit for 63 percent of patients, and that figure grew to more than 90 percent in extension trials. (See *BioWorld Today*, Feb. 1, 2011.)

NPS, of Bedminster, N.J., said it anticipates launching Gattex in the first quarter of 2013.

Friday's approval had little impact on the company's shares (NASDAQ:NPSP), which were down 10 cents at midday.