

NPS Pharmaceuticals Expects to File Natpara™ BLA in Mid-2013

The Associated Press

BEDMINSTER, N.J.--(BUSINESS WIRE)--Sep 5, 2012--NPS Pharmaceuticals, Inc. (NASDAQ: NPSP), a biopharmaceutical company developing innovative therapeutics for rare gastrointestinal and endocrine disorders, announced today that it expects to submit its Biologic License Application (BLA) for Natpara™ (recombinant human parathyroid hormone (rhPTH [1-84])) in mid-2013. The change in the company's forecasted timeline is due to a request from the Medical Device Division of the U.S. Food and Drug Administration (FDA) to modify the company's instructions for using the injection pen device to deliver Natpara. The FDA has not requested any new clinical data or clinical studies of Natpara. The requested changes will require the company to repeat its Usability Testing of the injection pen device using the modified instructions before submitting its BLA.

"I have every confidence that we will complete the requested testing of the injection pen instructions and deliver our BLA submission in line with our mid-2013 guidance," said Francois Nader, MD, president and chief executive officer of NPS Pharmaceuticals. "We are continuing to prepare the remaining components of the Natpara BLA to ensure that we assemble a high-quality submission. In addition, we are making good progress toward resolving the previously disclosed manufacturing issue and we fully believe this matter will be resolved well in advance of our BLA submission." Natpara has been classified by the FDA as a biologic-device combination. Usability Testing is used to show that a medical device, such as the injection pen used to deliver Natpara, is reasonably safe and effective when used by the intended user population. It involves conducting a simulated use test, in which prospective users operate the device in a meaningful way, in a realistic, but simulated environment.

About Hypoparathyroidism Hypoparathyroidism is a rare endocrine disorder in which the body produces insufficient levels of parathyroid hormone, the principal regulator of calcium and phosphorus. When the body has too little parathyroid hormone, blood calcium levels drop and phosphorus levels increase, which can cause a number of physical and mental symptoms, including uncontrollable muscle spasms and cramps, tetany, seizures, fatigue, anxiety, and depression. It is the only classic endocrine disorder for which there are no FDA-approved replacement therapies. Current treatment approaches focus on symptom management through high doses of calcium and active vitamin D supplementation, which can lead to serious side effects and long-term consequences. Over time, calcium may build up in the body and result in serious health risks, including calcifications in the kidneys, heart or brain.

About NPS Pharmaceuticals NPS Pharmaceuticals is a biopharmaceutical company focused on bringing orphan products to patients with rare disorders and few, if any,

NPS Pharmaceuticals Expects to File Natpara™ BLA in Mid-2013

Published on Medical Design Technology (<http://www.mdtmag.com>)

therapeutic options. NPS is advancing two late-stage registration programs. A New Drug Application is undergoing FDA review for Gattex® (teduglutide) as a treatment for adult short bowel syndrome (SBS) and a Phase 3 registration study has been completed for Natpara™ (recombinant human parathyroid hormone (rhPTH [1-84]) in adult hypoparathyroidism. NPS' earlier stage pipeline includes two calcilytic compounds, NPSP790 and NPSP795, with potential application in rare disorders involving increased calcium receptor activity, such as autosomal dominant hypocalcemia with hypercalciuria (ADHH). NPS complements its proprietary programs with a royalty-based portfolio of products and product candidates that includes agreements with Amgen, GlaxoSmithKline, Janssen Pharmaceuticals, Kyowa Hakko Kirin, and Nycomed (acquired by Takeda Pharmaceutical Company Limited).

"NPS," "NPS Pharmaceuticals," "Gattex," and "Natpara" are the company's trademarks. All other trademarks, trade names or service marks appearing in this press release are the property of their respective owners.

Statements made in this press release, which are not historical in nature, constitute forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. These statements are based on the company's current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Risks associated to the company's business include, but are not limited to, the risks associated with any failure by the company to successfully complete its preclinical and clinical studies within the projected time frames or not at all, the risk of not gaining marketing approvals for Gattex and Natpara, the risks associated with the company's strategy, as well as other risk factors described in the company's periodic filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K and Form 10-Qs. All information in this press release is as of the date of this release and NPS undertakes no duty to update this information.

CONTACT: NPS Pharmaceuticals, Inc.

Susan M. Mesco, 908-450-5516 smesco@npsp.com [1] www.npsp.com [2]

KEYWORD: UNITED STATES NORTH AMERICA CANADA NEW JERSEY INDUSTRY
KEYWORD: HEALTH BIOTECHNOLOGY MEDICAL DEVICES PHARMACEUTICAL FDA
GENERAL HEALTH SOURCE: NPS Pharmaceuticals, Inc. Copyright Business Wire
2012 PUB: 09/05/2012 08:15 AM/DISC: 09/05/2012 08:15 AM
<http://www.businesswire.com/news/home/20120905006002/> [3]

Source URL (retrieved on 05/21/2013 - 12:05am):

<http://www.mdtmag.com/news/2012/09/nps-pharmaceuticals-expects-file-natpara%E2%84%A2-bla-mid-2013>

Links:

[1] <mailto:smesco@npsp.com>

[2] <http://www.npsp.com>

NPS Pharmaceuticals Expects to File Natpara™ BLA in Mid-2013

Published on Medical Design Technology (<http://www.mdtmag.com>)

[3] <http://www.businesswire.com/news/home/20120905006002/>