Progenics Announces Results of Methylnaltrexone Phase 3 Safety Study in Chronic, Non-Malignant Pain Patients

Drug Generally Safe and Well Tolerated With Durable Clinical Responses in One-Year Study

TARRYTOWN, N.Y., May 20, 2011 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX) today provided analyses of safety and efficacy endpoints from the 1,034-patient, one-year phase 3 safety study of methylnaltrexone bromide subcutaneous injection in non-malignant pain patients with opioid-induced constipation (OIC). At a fixed dose of 12 mg, the drug was shown to be generally safe and well tolerated, with a safety profile similar to that from a previously reported, shorter-duration efficacy study in non-malignant pain patients. The results are being presented at the annual meeting of the American Pain Society in Austin, TX, May 19-21, 2011.

Patients experienced consistent results across all monthly intervals, and 34.1% of methylnaltrexone 12 mg subcutaneous injections resulted in bowel movements within four hours during the treatment period. In addition, patient subjective assessments showed statistically significant improvements from baseline for a reduction in straining and for the number of bowel movements accompanied by the sensation of complete evacuation.

"This study yielded safety and efficacy data that support the potential utility of subcutaneous methylnaltrexone for use by patients who take opioids for pain over extended periods," said Robert Israel, M.D., senior vice president of medical affairs at Progenics. "We found that the four-hour response rate remained durable over the course of the one-year study period. In addition, the assessed safety of long-term methylnaltrexone use was consistent with previously reported results of the three-month phase 3 efficacy study in non-malignant pain patients with OIC."

The safety study included patients who had a history of chronic, non-malignant pain (including back pain, joint/extremity pain, neurologic/neuropathic pain and fibromyalgia) and who experienced constipation resulting from opioid pain medication use for at least one month prior to screening. Of the 1,034 patients who received at least one dose of methylnaltrexone, 624 patients were treated for six months or more, and 477 completed the 48-week study and post-treatment follow-up periods. Patients took a median of six subcutaneous injections per week of methylnaltrexone 12 mg for up to 48 weeks. There were no observed unexpected safety signals, or cases of gastrointestinal perforation in the study. Pain scores and opioid use data confirmed that methylnaltrexone 12 mg subcutaneous injection did not interfere with analgesia or cause opioid withdrawal symptoms.

These safety data, together with previously announced efficacy data, complete the major data packages for a supplemental New Drug Application being prepared for submission to the U.S. Food and Drug Administration by the end of June. In this application, Progenics and its commercialization partner, Salix Pharmaceuticals (Nasdaq:SLXP), plan to seek approval for subcutaneous methylnaltrexone in non-malignant pain patients suffering from opioid-induced constipation. Methylnaltrexone currently is approved and marketed as RELISTOR® for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.

Copies of the posters used in Progenics' presentations are available to view in the Events section of its website, www.progenics.com.

Study Design

This 52-week, phase 3, multi-center, international, open-label study of subcutaneous methylnaltrexone enrolled patients with chronic, non-malignant pain who were receiving stable (≥1 month) doses of opioids. A two week screening period was followed by a 48-week, open-label dose administration period and a two week, post-treatment follow-up period. Study participants were instructed to self-administer methylnaltrexone daily at a dose of 12 mg. Use of routine laxatives was permitted for the duration of the study.

About Opioids, Constipation and RELISTOR (methylnaltrexone bromide)

Opioid analgesics frequently are prescribed to manage pain in patients with advanced illness. Constipation commonly occurs in such patients, as opioids, which relieve pain by specifically interacting with mu-opioid receptors within the brain and spinal cord of the central nervous system (CNS), also interact with such receptors outside the CNS, including in the gastrointestinal tract. The resulting constipation can be debilitating. RELISTOR is a peripherally acting mu-opioid receptor antagonist that decreases the constipating effects of opioid pain medications, without affecting their ability to relieve pain, by selectively displacing opioids

from such receptors in the gastrointestinal tract and thereby decreasing their constipating effects. Because of its chemical structure, RELISTOR does not affect opioid-mediated analgesic effects on the CNS. RELISTOR is the first approved medication that specifically targets the underlying cause of OIC.

About RELISTOR

RELISTOR subcutaneous injection is approved in the United States for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. The drug also is approved for use in over 50 countries worldwide, including the European Union, Canada and Australia. Applications in additional countries are pending.

Important Safety Information for RELISTOR

RELISTOR is indicated for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Use of RELISTOR beyond four months has not been studied in the advanced illness population.

RELISTOR is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician.Use of RELISTOR has not been studied in patients with peritoneal catheters.

Safety and efficacy of RELISTOR have not been established in pediatric patients.

Rare cases of gastrointestinal (GI) perforation have been reported in advanced illness patients with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the GI tract (i.e., cancer, peptic ulcer, Ogilvie's syndrome). Perforations have involved varying regions of the GI tract (e.g., stomach, duodenum, and colon).

Use RELISTOR with caution in patients with known or suspected lesions of the GI tract. Advise patients to discontinue therapy with RELISTOR and promptly notify their physician if they develop severe, persistent, and/or worsening abdominal symptoms.

The most common adverse reactions reported with RELISTOR compared with placebo in clinical trials were abdominal pain (28.5% vs. 9.8%), flatulence (13.3% vs. 5.7%), nausea (11.5% vs. 4.9%), dizziness (7.3% vs. 2.4%), diarrhea (5.5% vs. 2.4%), and hyperhidrosis (6.7% vs. 6.5%).

RELISTOR full Prescribing Information for the U.S. is available at www.relistor.com.

Related Development Programs

Subcutaneous methylnaltrexone in chronic, non-malignant pain patients with OIC

The 1,034-patient, one-year, open-label, international, phase 3 safety study (reported on in this press release) to evaluate the long-term safety and tolerability of methylnaltrexone bromide subcutaneous injection in chronic, non-malignant pain patients with opioid-induced constipation was completed in September 2010. Progenics and its commercialization partner, Salix Pharmaceuticals, plan to submit a supplemental New Drug Application for this potential indication to the U.S. FDA by the end of second quarter 2011.

Oral methylnaltrexone in chronic, non-malignant pain patients with OIC

Progenics and Salix expect to complete enrollment in a 700-patient, international, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of oral methylnaltrexone to treat opioid-induced constipation in non-malignant pain patients by the end of September 2011.

About Progenics

Progenics Pharmaceuticals, Inc., of Tarrytown, NY, is a biopharmaceutical company with programs in gastroenterology, oncology and virology focused on innovative therapeutics for patients with debilitating conditions and life-threatening diseases. Progenics' first commercialized therapy is RELISTOR® (methylnaltrexone bromide), a first-in-class treatment for opioid-induced constipation approved in more than 50 countries for patients with advanced illness. Progenics has exclusively licensed Salix Pharmaceuticals, Ltd. to continue development and commercialization of RELISTOR in markets worldwide other than Japan, where Ono Pharmaceutical Co., Ltd. has an exclusive license to develop and commercialize subcutaneous RELISTOR. Progenics' pipeline candidates include PSMA ADC, a human monoclonal antibody-drug conjugate in phase 1 testing for treatment of prostate cancer, and preclinical stage, novel antibodies directed at toxins produced by *C. difficile* bacteria.

The Progenics logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=9678

Editors Note:

For more information, please visit www.progenics.com.

(PGNX-C)

Please Note: *The information in this press release may contain projections and other forward-looking statements regarding future events. Such statements are predictions and are subject to risks and uncertainties that could cause actual events or results to differ materially. These risks and uncertainties include, among others, the cost, timing and results of clinical trials and other development activities; the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational NDAs; market acceptance for approved products; generic and other competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; and possible safety or efficacy concerns, general business, financial and accounting risks and litigation. More information concerning Progenics and such risks and uncertainties is available on its website, as well as in its press releases and reports it files with the U.S. Securities and Exchange Commission. Progenics is providing the information in this press release as of its date and does not undertake any obligation to update or revise it, whether as a result of new information, future events or circumstances or otherwise.*

Additional information concerning Progenics and its business may be available in press releases or other public announcements and public filings made after this release.

CONTACT: Investors:

Amy Martini

Corporate Affairs

(914) 789-2816

amartini@progenics.com

Media:

Aline Schimmel

Scienta Communications

(312) 238-8957

aschimmel@scientapr.com

Source: Progenics Pharmaceuticals Inc.

News Provided by Acquire Media