



Progenics and Salix Announce FDA Acceptance of sNDA Filing for RELISTOR® in Patients with Non-Cancer Pain

— PDUFA Action Date is April 27, 2012 —

TARRYTOWN, N.Y. & RALEIGH, N.C., Aug. 30, 2011--(BUSINESS WIRE)-- Progenics Pharmaceuticals, Inc. (NASDAQ:PGNX) and Salix Pharmaceuticals, Ltd. (NASDAQ:SLXP) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing a supplemental New Drug Application (sNDA) for RELISTOR (methylnaltrexone bromide) Subcutaneous Injection to treat opioid-induced constipation (OIC) in patients with non-cancer pain. The FDA has issued an action date of April 27, 2012 under the Prescription Drug User Fee Act (PDUFA).

RELISTOR is a peripherally acting mu-opioid receptor antagonist that counteracts the constipating effects of opioid pain medications in the gastrointestinal tract without affecting their ability to relieve pain. RELISTOR Subcutaneous Injection has been FDA approved since 2008 to treat 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.

Bill Forbes, Pharm.D., executive vice president, research and development, and chief development officer at Salix said, "Acceptance of this filing for FDA review is a significant step toward gaining approval for RELISTOR to treat the underlying cause of OIC experienced by the millions of patients taking opioids for non-cancer pain."

Robert J. Israel, senior vice president of medical affairs for Progenics, added, "This sNDA includes results from 31 studies involving more than 4,000 patients. We are pleased to have the FDA review these data in support of RELISTOR's safety and efficacy in a new indication."

About Opioids, Constipation and RELISTOR (methylnaltrexone bromide)

Opioid analgesics are frequently prescribed to manage pain in patients with advanced illness. Constipation commonly occurs in palliative-care patients receiving opioid therapy for pain. RELISTOR is the first approved medication that specifically targets the underlying cause of OIC in these patients, when response to laxatives has been insufficient. Opioids relieve pain by specifically interacting with mu-opioid receptors within the brain and spinal cord. However, opioids also interact with mu-opioid receptors found outside the central nervous system, such as those within the gastrointestinal tract, resulting in constipation that can be debilitating. RELISTOR (methylnaltrexone bromide) is a peripherally acting mu-opioid receptor antagonist that decreases the constipating effects of opioid pain medications without affecting their ability to relieve pain. RELISTOR selectively displaces opioids from the mu-opioid receptors outside the CNS, including those located in the gastrointestinal tract, thereby decreasing their constipating effects. Because of its chemical structure, RELISTOR does not affect opioid-mediated analgesic effects on the CNS.

RELISTOR Subcutaneous Injection is approved in the United States for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. The use of RELISTOR beyond four months has not been studied. The drug is also approved for use in over 50 countries worldwide, including the European Union, Canada, and Australia. In the 27 member states of the E.U., as well as Iceland, Norway and Liechtenstein, RELISTOR is approved for the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. In Canada, the drug is approved for the treatment of opioid-induced constipation in patients with advanced illness, receiving palliative care. When response to laxatives has been insufficient, RELISTOR should be used as an adjunct therapy to induce a prompt bowel movement. Applications in additional countries are pending. RELISTOR is under license to Salix Pharmaceuticals and Ono Pharmaceutical from Progenics Pharmaceuticals.

For more information about RELISTOR, please visit www.RELISTOR.com.

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.

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, 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.

About Progenics

Progenics Pharmaceuticals, Inc., of Tarrytown, New York, 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 worldwide markets 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 to toxins produced by *C. difficile* bacteria.

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

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About Salix

Salix Pharmaceuticals, Ltd., headquartered in Raleigh, North Carolina, develops and markets prescription pharmaceutical products for the prevention and treatment of gastrointestinal diseases. Salix's strategy is to in-license late-stage or marketed proprietary therapeutic drugs, complete any required development and regulatory submission of these products, and market them through the Company's gastroenterology specialty sales and marketing team.

Salix markets XIFAXAN[®] (rifaximin) tablets 200 mg and 550 mg, MOVIPREP[®] (PEG 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid for oral solution), OSMOPREP[®] (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets, VISICOL[®] (sodium phosphate monobasic monohydrate, USP, and sodium phosphate dibasic anhydrous, USP) Tablets, APRISO[™] (mesalamine) extended-release capsules 0.375 g, METOZOLV[®] ODT (metoclopramide HCl), RELISTOR[®] (methylnaltrexone bromide) Subcutaneous Injection, PEPCID[®] (famotidine) for Oral Suspension, Oral Suspension DIURIL[®] (Chlorothiazide), AZASAN[®] (Azathioprine) Tablets, USP, 75/100 mg, ANUSOL-HC[®] 2.5% (Hydrocortisone Cream, USP), ANUSOL-HC[®] 25 mg Suppository (Hydrocortisone Acetate), PROCTOCORT[®] Cream (Hydrocortisone Cream, USP) 1% and PROCTOCORT[®] Suppository (Hydrocortisone Acetate Rectal Suppositories) 30 mg. Crofelemer, budesonide foam, RELISTOR[®], Lumacan[®] and rifaximin for additional indications are under development.

For full prescribing information and important safety information on Salix products, including BOXED WARNINGS for VISICOL, OSMOPREP and METOZOLV, please visit www.salix.com where the Company promptly posts press releases, SEC filings and other important information or contact the Company at 919-862-1000.

Salix trades on the NASDAQ Global Select Market under the ticker symbol "SLXP".

For more information about Salix, please visit our Website at www.salix.com or contact the Company at 919-862-1000. Follow us on Twitter (@SalixPharma) and Facebook (www.facebook.com/SalixPharma). Information on our web site is not incorporated

in our SEC filings.

Please Note: The materials provided herein contain projections and other forward—looking statements regarding future events. Such statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational NDAs; market acceptance for approved products; the cost, timing and results of clinical trials and other development activities involving pharmaceutical products; generic and other competition; litigation and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties in an increasingly global industry; and revenue recognition and other critical accounting policies. More information concerning Progenics and Salix is available on the companies' websites, as well as in press releases and reports they file with the U.S. Securities and Exchange Commission.

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