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Sucampo Pharmaceuticals Announces FDA Acceptance of sNDA for AMITIZA in Children with Pediatric Functional Constipation, with Priority Review Designation

ROCKVILLE, Md., Sept. 28, 2017 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (NASDAQ:SCMP), a global biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing its recently submitted supplemental New Drug Application (sNDA) for lubiprostone (AMITIZA®) in children aged 6 to 17 years with pediatric functional constipation. The filing has received Priority Review designation from the FDA.

Priority Review status is designated for drugs that may offer major advances in treatment or provide a treatment where no adequate therapy exists. The granting of Priority Review status accelerates the timing of the FDA review of the sNDA application. The FDA has assigned a user fee goal date of January 28, 2018.

“We are pleased with the FDA’s acceptance of the sNDA filing with Priority Review, as this underscores the need for prescription options for children 6 to 17 years of age suffering from pediatric functional constipation,” said Peter Greenleaf, Chairman and Chief Executive Officer of Sucampo. “If approved, AMITIZA would be the first and only prescription medication specifically for these pediatric patients, who currently have limited options to address their underlying functional constipation.”

Earlier this week Sucampo also announced that a Phase 3 study to evaluate the bioequivalence of sprinkle and capsule formulations of lubiprostone (AMITIZA®) as compared to placebo in adult subjects with chronic idiopathic constipation (CIC) did not show bioequivalence, but did demonstrate significant activity and was well-tolerated. Sucampo’s focus continues to be on the potential approval of the pediatric indication and will not be moving forward with an NDA submission for the sprinkle formulation in adults. Sucampo will continue to have discussions with the FDA in the coming months about the ongoing pediatric functional constipation program in younger children ages 6 months through 5 years of age.

About lubiprostone (AMITIZA®)

AMITIZA (lubiprostone) is a chloride channel activator that acts locally in the small intestine. By increasing intestinal fluid secretion, lubiprostone increases motility in the intestine, thereby facilitating the passage of stool and alleviating symptoms associated

with chronic idiopathic constipation. Lubiprostone, via activation of apical CIC-2 channels in intestinal epithelial cells, bypasses the antisecretory action of opiates that results from suppression of secretomotor neuron excitability. Activation of CIC-2 by lubiprostone has also been shown to stimulate recovery of mucosal barrier function and reduce intestinal permeability via the restoration of tight junction protein complexes in ex vivo studies of ischemic porcine intestine.

AMITIZA (24 mcg twice daily) is indicated in the U.S. for the treatment of adults with CIC and opioid induced constipation (OIC) with chronic, non-cancer pain, including chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dose escalation. The effectiveness in patients with OIC taking diphenylheptane opioids (e.g. methadone) has not been established. AMITIZA (8 mcg twice daily) is also approved in the U.S. for irritable bowel syndrome with constipation (IBS-C) in women 18 years of age and older. In Japan, AMITIZA (24 mcg twice daily) is indicated for the treatment of chronic constipation (excluding constipation caused by organic diseases). AMITIZA is also approved in select other markets for constipation indications.

Important Safety Information

AMITIZA (lubiprostone) is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be thoroughly evaluated by the treating healthcare provider (HCP) to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.

Patients taking AMITIZA may experience nausea. Concomitant administration of food with AMITIZA may reduce symptoms of nausea.

Avoid use of AMITIZA in patients with severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment. Instruct patients to discontinue AMITIZA and contact their HCP if severe diarrhea occurs.

Syncope and hypotension have been reported with AMITIZA in the postmarketing setting and a few of these adverse reactions resulted in hospitalization. Most reports occurred in patients taking 24 mcg twice daily. Patients should be aware that the risk of syncope and hypotension may be increased with concomitant diarrhea, vomiting, or use of medications known to lower blood pressure. Inform patients that syncope and hypotension may occur within an hour of the first dose or subsequent doses of AMITIZA and generally resolve prior to the next dose, but may recur with repeat dosing. Instruct patients to discontinue AMITIZA and contact their HCP if these reactions occur.

Dyspnea may occur within an hour of first dose. This symptom generally resolves within three hours, but may recur with repeat dosing. Instruct patients to contact their HCP if dyspnea occurs. Some patients have discontinued therapy because of dyspnea.

In clinical trials of AMITIZA (24 mcg twice daily vs placebo; N=1113 vs N=316, respectively) in patients with CIC, the most common adverse reactions (incidence > 4%) were nausea (29% vs 3%), diarrhea (12% vs 1%), headache (11% vs 5%), abdominal pain (8% vs 3%), abdominal distension (6% vs 2%), and flatulence (6% vs 2%).

In clinical trials of AMITIZA (24 mcg twice daily vs placebo; N=860 vs N=632, respectively) in patients with OIC, the most common adverse reactions (incidence > 4%) were nausea (11% vs 5%) and diarrhea (8% vs 2%).

In clinical trials of AMITIZA (8 mcg twice daily vs placebo; N=1011 vs N=435, respectively) in patients with IBS-C, the most common adverse reactions (incidence > 4%) were nausea (8% vs 4%), diarrhea (7% vs 4%), and abdominal pain (5% vs 5%).

Concomitant use of diphenylheptane opioids (e.g., methadone) may interfere with the efficacy of AMITIZA.

The safety of AMITIZA in pregnancy has not been evaluated in humans. Based on animal data, AMITIZA may cause fetal harm. AMITIZA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when AMITIZA is administered to a nursing woman. Advise nursing women to monitor infants for diarrhea.

Reduce the dosage in CIC and OIC patients with moderate and severe hepatic impairment. Reduce the dosage in IBS-C patients with severe hepatic impairment.

About Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of highly specialized medicines. Sucampo has a late-stage pipeline of product candidates in clinical development for orphan disease areas, including VTS-270, a mixture of 2-hydroxypropyl-B-cyclodextrins with a specific compositional fingerprint that has been granted orphan designation in the U.S. and Europe and is in a pivotal Phase 2/3 clinical trial for the treatment of Niemann-Pick Disease Type C-1, a rare progressive genetic disorder. VTS-270 has also been granted breakthrough therapy designation in the U.S. Sucampo has an exclusive option for the North American rights to CPP-1X/sulindac, which is in Phase 3 development for the treatment of familial adenomatous polyposis and has been granted orphan drug designation in the U.S. The company has two marketed products – AMITIZA and RESCULA. For more information, please visit www.sucampo.com.

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Sucampo Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding financial results, product development, and

other statements that are not historical facts. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; Sucampo's ability to accurately predict future market conditions; Sucampo's ability to successfully integrate the operations of acquired businesses; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the effects of competitive products on Sucampo's products; and the exposure to litigation and/or regulatory actions.

No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 10-K as filed with the Securities and Exchange Commission on March 8, 2017, as well as its filings with the Securities and Exchange Commission on Forms 8-K and 10-Q since the filing of the Form 10-K, all of which Sucampo incorporates by reference.

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