

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 19, 2012

Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

30-0520478

(State or Other Jurisdiction
of Incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

4520 East-West Highway, 3rd Floor
Bethesda, Maryland

20814

(Address of Principal Executive Offices)

(Zip Code)

Registrant's telephone number, including area code: (301) 961-3400

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On September 25, 2012, Sucampo Pharmaceuticals, Inc. ("Sucampo") and Takeda Pharmaceuticals U.S.A., Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted priority review status to their filing of a supplemental new drug application (sNDA).

The sNDA was filed in late July seeking approval for an additional indication for AMITIZA[®] (lubiprostone) for the treatment of opioid-induced constipation (OIC) in patients with chronic, non-cancer pain.

The FDA's priority review, which allows for an abbreviated review period of six months, is granted to drugs that offer either significant advances in treatment or provide a treatment where there is no existing adequate therapy. As a result of this priority review, Sucampo and Takeda expect the FDA's decision by late January 2013.

"One of the most common adverse reactions of opioid medications is opioid-induced constipation, a medical condition for which there are currently no approved oral prescription treatment options available," said Dr. Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman, Chief Scientific Officer, and Chief Executive Officer of Sucampo. "The priority review of this sNDA application underscores that the management of OIC is an unmet need of patients with chronic pain and highlights the need for new therapies to address this condition."

The information in this Item 8.01 and Exhibit 99.1 to this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits

The following exhibit relating to Item 8.01 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by the registrant on September 25, 2012.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SUCAMPO PHARMACEUTICALS, INC.

Date: September 25, 2012

By: /s/ THOMAS J. KNAPP

Name: Thomas J. Knapp

Title: Executive Vice President, Chief Legal
Officer & Corporate Secretary

U.S. Food and Drug Administration Grants Priority Review Status to AMITIZA[®] (lubiprostone) Submission Seeking Approval for Treatment of Opioid-induced Constipation

BETHESDA, Md. & DEERFIELD, Ill.--(BUSINESS WIRE)--September 25, 2012--Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP) (SPI) and Takeda Pharmaceuticals U.S.A., Inc. (TPUSA) today announced that the U.S. Food and Drug Administration (FDA) has granted priority review of their supplemental new drug application (sNDA) filing. The sNDA was filed in late July seeking approval for an additional indication for AMITIZA[®] (lubiprostone) for the treatment of opioid-induced constipation (OIC) in patients with chronic, non-cancer pain.

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"One of the most common adverse reactions of opioid medications is opioid-induced constipation, a medical condition for which there are currently no approved oral prescription treatment options available," said Dr. Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman, Chief Scientific Officer, and Chief Executive Officer. "The priority review of this sNDA application underscores that the management of OIC is an unmet need of patients with chronic pain and highlights the need for new therapies to address this condition."

About AMITIZA

AMITIZA (lubiprostone) is a chloride channel activator indicated for the treatment of chronic idiopathic constipation (CIC) (24 mcg twice daily) in adults and for irritable bowel syndrome with constipation (8 mcg twice daily) in women 18 years of age and older by the FDA in the United States. AMITIZA (lubiprostone) is approved in Japan for the treatment of chronic constipation (excluding constipation caused by organic diseases); in Switzerland for CIC; and in the United Kingdom for CIC.

Important Safety Information

AMITIZA 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 to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.

The safety of AMITIZA in pregnancy has not been evaluated in humans. AMITIZA should be used during pregnancy only if the benefit justifies the potential risk to the fetus. Women who could become pregnant should have a negative pregnancy test prior to beginning therapy with AMITIZA and should be capable of complying with effective contraceptive measures.

Patients taking AMITIZA may experience nausea. If this occurs, concomitant administration of food with AMITIZA may reduce symptoms of nausea. Patients who experience severe nausea should inform their healthcare provider.

AMITIZA should not be prescribed to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment and inform their healthcare provider if the diarrhea becomes severe.

Patients taking AMITIZA may experience dyspnea within an hour of first dose. This symptom generally resolves within three hours, but may recur with repeat dosing. Patients who experience dyspnea should inform their healthcare provider. Some patients have discontinued therapy because of dyspnea.

In clinical trials of AMITIZA (24 mcg twice daily vs. placebo; N=1113 vs. N=316) in patients with Chronic Idiopathic Constipation (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 (8 mcg twice daily vs. placebo; N=1011 vs. N=435) in patients with Irritable Bowel Syndrome with Constipation (IBS-C), the most common adverse reactions (incidence > 4%) were nausea (8% vs. 4%), diarrhea (7% vs. 4%), and abdominal pain (5% vs. 5%).

Reduce the dosage in CIC 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 global pharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs based on prostanes. The therapeutic potential of prostanes, which occur naturally in the human body as a result of enzymatic (15-PGDH) transformation of certain fatty acids, was first identified by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo Pharmaceuticals' Chairman and Chief Executive Officer. Dr. Ueno founded Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, Ph.D., founding Chief Executive Officer. For more information, please visit www.sucampo.com.

AMITIZA is a registered trademark of Sucampo Pharmaceuticals, Inc.

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 product development, product potential, future financial and operating results, 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; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally 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 presentation 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 Form 10-K for the year ended Dec. 31, 2011, which the Company incorporates by reference.

Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. are subsidiaries of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. The respective companies currently market oral diabetes, insomnia, rheumatology, gastroenterology, and cardiovascular treatments and seek to bring innovative products to patients through a pipeline that includes compounds in development for metabolic and cardiovascular disease, gastroenterology, neurology and other conditions. To learn more about these Takeda companies, visit www.takeda.us.

Takeda Forward-Looking Statement

This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the United States and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.

The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.

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