

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): February 2, 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, Suite 300
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))
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Item 8.01. Other Events.

On February 2, 2012, Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals, U.S.A., Inc. announced that lubiprostone met the primary endpoint in a phase 3 clinical trial for the treatment of opioid-induced bowel dysfunction in patients with chronic, non-cancer pain, excluding those taking methadone.

The full text of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

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

99.1 Press Release issued by the registrant on February 2, 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: February 7, 2012

By: /s/ THOMAS J. KNAPP

Name: Thomas J. Knapp

Title: Sr. VP, General Counsel & Corporate Secretary

Lubiprostone Meets Primary Endpoint in Phase 3 Clinical Trial for Opioid-Induced Bowel Dysfunction (OBD)***Aim to File for Approval of Lubiprostone as First Oral Drug for Prescription-based Treatment of OBD******Anticipate sNDA Filing in US in First Half of 2012***

BETHESDA, Md. & DEERFIELD, Ill.--(BUSINESS WIRE)--February 2, 2012--Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP) (SPI) and Takeda Pharmaceuticals U.S.A., Inc. announced today that lubiprostone met the primary endpoint in a phase 3 clinical trial for the treatment of opioid-induced bowel dysfunction (OBD) in patients with chronic, non-cancer pain, excluding those taking methadone.

Patients received lubiprostone 24-mcg capsule or placebo capsule twice daily for 12 weeks. The primary endpoint was the overall spontaneous bowel movement (SBM) response rate. The response rate for lubiprostone-treated patients was 26.9% (n=219) versus 18.6% (n=220) for placebo-treated patients (p=0.035).

M. Mazen Jamal, M.D., M.P.H., Chief of Endoscopy, Long Beach Veterans Affairs' Medical Center, Long Beach, California, Professor, Department of Medicine, University of California College of Medicine at Irvine, an investigator in the trial, said, "The results from this Phase 3 trial demonstrate that lubiprostone has the potential to be the first FDA-approved orally administered medicine with the indication to treat OBD in non-cancer, non-methadone patients. OBD can be a painful and debilitating side effect affecting many non-cancer pain patients taking opioids chronically. There are more than 200 million prescriptions for opioid use in the U.S. annually and a substantial portion of these prescriptions are for non-cancer chronic pain. Many patients are not getting the desired relief and there is a significant need for a new medicine to treat this condition."

Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman and CEO of SPI, commented, "These data confirm the results from a previous phase 3 trial of lubiprostone in OBD patients and together with data from the associated long-term safety trial, complete what we believe are the data requirements to support the submission of a supplemental New Drug Application (sNDA). We expect to submit the sNDA to the U.S. Food and Drug Administration (FDA) in the first half of 2012. In addition, we will discuss the potential for priority review, as we believe that physicians and their patients are actively seeking new therapies to address this condition. If approved, lubiprostone could be the first orally-administered medicine with the indication for OBD, providing another option for patients who need it and further differentiating lubiprostone from the competition."

About this phase 3 trial of lubiprostone in OBD

This phase 3 trial was a randomized, placebo-controlled double-blinded trial of the efficacy and safety of lubiprostone in patients with opioid-induced bowel dysfunction. The trial enrolled and treated a total of 439 patients in the U.S. and Europe. Patients were evenly randomized to receive either placebo or lubiprostone 24-mcg gel capsule twice daily throughout the 12-week treatment period. Eligible patients must have been treated for chronic, non-cancer related pain with any opioid other than methadone for at least 30 days prior to screening, and continued opioid therapy throughout the study. Patients were confirmed to have OBD, which is defined as having an average of fewer than three SBMs per week during the three-week screening period and at least one of the following for at least 25 percent of SBMs during each week of the screening period: hard or very hard stools; sensation of incomplete evacuation; moderate to very severe straining associated with SBMs.

Responders were determined based on patients' daily record of bowel movements. In order to be defined as a treatment responder, patients were required to demonstrate at least ≥ 1 SBM improvement over baseline SBM frequency for all treatment weeks for which observed data were available, and must additionally have demonstrated a full response (≥ 3 SBMs per week) for at least 9 of the 12 treatment weeks. An SBM was defined as any BM that does not occur within 24 hours after rescue medication use.

There were no drug-related serious adverse events reported for patients taking lubiprostone. Overall, the percentage of patients discontinuing treatment due to adverse events was 5.9% for the lubiprostone group compared with 2.3% in the placebo group. The most common treatment-related adverse events (experienced by >5 percent of patients) were diarrhea (9.6% vs. 1.4%), nausea (8.2% vs. 2.7%), and abdominal pain (5.5% vs. 0.0%) for lubiprostone vs. placebo, respectively. A majority (91.7%) of lubiprostone patients who reported diarrhea described the events as mild to moderate in severity. The incidence rates of severe nausea were 1.4% for placebo-treated patients and 0.9% for lubiprostone treated patients.

"We at Takeda are pleased that this study met its primary endpoint and will continue to work closely with our partner, Sucampo, in preparing for the anticipated sNDA filing this year," said Gilles Delecoeuillerie, M.D., Ph.D., Executive Medical Director for Gastroenterology at Takeda.

Results of this Phase 3 trial will be submitted for presentation at an appropriate medical meeting and for publication in an appropriate peer-reviewed journal.

About Opioid-induced Bowel Dysfunction (OBD)

OBD comprises a variety of gastrointestinal conditions brought on by the use of opioid-based medications such as morphine and codeine. OBD encompasses a range of adverse gastrointestinal effects which includes severe constipation, infrequent and incomplete bowel movements, hard stool consistency, straining associated with bowel movements and abdominal discomfort/pain and bloating. Opioid drugs are used to treat moderate to severe pain. Constipation is one of the most common side effects of opioids, affecting up to 81% of patients, and rarely spontaneously resolves without treatment. Despite their pain-relieving efficacy, opioids are known to produce gastrointestinal effects that lead to OBD, including inhibition of large intestine motility, decreased gastric emptying and hard stools. In addition to a delay in intestinal transit, the reduction in secretion, upregulation of water and absorption of electrolytes in the gut may contribute to the constipating effects of opioids. In a 2011 Cochrane Collaboration Review on the use of laxatives in opioid pain patients (palliative care) they reported there have been no randomized clinical trials on any laxative that evaluated laxation response rates, patient tolerability and acceptability. Some patients discontinue opioid therapy and thereby endure pain rather than suffer from the constipation the opioids cause.

About AMITIZA for Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C)

AMITIZA is a chloride channel activator indicated for the treatment of CIC (24 mcg twice daily) in adults and for IBS-C (8 mcg twice daily) in women 18 years of age and older.

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.

For further information please see complete Prescribing Information and visit www.amitiza.com.

About Sucampo Pharmaceuticals

Sucampo Pharmaceuticals, Inc. is an international biopharmaceutical company focused on the discovery, development and commercialization of medicines based on prostones. The therapeutic potential of prostones, 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, MD, PhD, PhD, Sucampo Pharmaceuticals' Chairman and Chief Executive Officer. Dr. Ueno founded Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, PhD, founding Chief Executive Officer and currently Executive Advisor, International Business Development and a member of the Board of Directors. For more information about Sucampo Pharmaceuticals, please visit www.sucampo.com.

About 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 diabetes, cardiovascular disease, gastroenterology, neurology and other conditions. To learn more about these Takeda companies, visit www.tpna.com.

Sucampo Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Sucampo Pharmaceuticals are forward-looking statements made under the provisions of The Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "should," "would," "could," "will," "may" or other similar expressions. Forward-looking statements include statements about the potential utility of AMITIZA[®] to treat particular indications and expected data availability dates. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those described in Sucampo Pharmaceuticals' filings with the Securities and Exchange Commission (SEC), including the annual report on Form 10-K for the year ended December 31, 2010 and other periodic reports filed with the SEC. Any forward-looking statements in this press release represent Sucampo Pharmaceuticals' views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Sucampo Pharmaceuticals anticipates that subsequent events and developments will cause its views to change. However, while Sucampo Pharmaceuticals may elect to update these forward-looking statements publicly at some point in the future, Sucampo Pharmaceuticals specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

Takeda Forward-Looking Statement Disclaimer

This press release contains forward-looking statements about Takeda. 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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