

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): May 13, 2009

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))
-

**Item 7.01. Regulation FD Disclosure.**

On May 19, 2009, Sucampo Pharmaceuticals, Inc. issued a press release. The full text of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference. All readers are encouraged to read the entire text of the press release attached hereto.

In accordance with General Instruction B.2. of Form 8-K, the information presented under this Item 7.01 and attached as Exhibit 99.1, except insofar as such information is also set forth under Item 8.01 below, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

**Item 8.01. Other Events.**

Sucampo Pharmaceuticals, Inc., today announced that its subsidiary, Sucampo Pharma, Ltd., or SPL, has initiated enrollments and completed the randomizations of the first patients into the pivotal phase 3 efficacy trial and an open-label phase 3 safety trial of lubiprostone for chronic idiopathic constipation, or CIC, in Japan.

Under the terms of the February 19, 2009 agreement between SPL and Abbott Japan Co. Ltd., or Abbott Japan, to develop and commercialize lubiprostone in Japan for the treatment of CIC, SPL will receive from Abbott Japan a development milestone payment of \$7.5 million within 15 days of the initiation of the first phase 3 trial of lubiprostone, which occurred on May 13, 2009.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by the registrant on May 19, 2009.

---

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: May 19, 2009

/s/ JAN SMILEK

Name: Jan Smilek

Title: Chief Financial Officer

---

## EXHIBIT INDEX

Exhibit No.

Description

99.1

Press release issued by the registrant on May 19, 2009

## Sucampo Initiates Pivotal Phase 3 Efficacy Trial of Lubiprostone for Chronic Idiopathic Constipation in Japan

BETHESDA, Md.--(BUSINESS WIRE)--May 19, 2009--Sucampo Pharmaceuticals, Inc. (NASDAQ:SCMP), an international biopharmaceutical company, today announced that its subsidiary, Sucampo Pharma, Ltd., has initiated enrollment and completed the randomization of the first patient into the pivotal phase 3 efficacy trial of lubiprostone for chronic idiopathic constipation (CIC) in Japan.

Under the terms of a license, commercialization and supply agreement Sucampo signed in February 2009 with Abbott Japan Co., Ltd., Sucampo will receive a milestone payment in the amount of \$7.5 million in recognition of this achievement. Abbott has exclusive rights to market lubiprostone in Japan for the treatment of CIC.

Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman and Chief Executive Officer of Sucampo Pharmaceuticals, Inc., said, "We remain committed to our goal of broad international expansion of lubiprostone and this efficacy trial will increase our experience with the drug in the Japanese population."

This pivotal phase 3 double-blinded, placebo-controlled clinical trial is designed to evaluate the efficacy and safety of lubiprostone in Japanese patients with CIC over a 28-day treatment period. Patients will receive one lubiprostone 24-mcg, or placebo, capsule twice a day. This trial seeks to enroll approximately 116 patients, each of whom have a history of fewer than three spontaneous bowel movements (SBMs) per week for at least six months, as confirmed during a 14-day screening period. The primary efficacy endpoint is the change in SBMs at the end of the first week of treatment.

Sucampo also has initiated enrollment and initial dosing of Japanese CIC patients, for up to 48 weeks of treatment, in an open-label phase 3 safety trial of lubiprostone (trade name Amitiza<sup>®</sup>). This is an open-label, multi-center, confirmatory trial in which patients will receive one 24-mcg lubiprostone capsule twice a day. This trial seeks to enroll 200 patients, each of whom has a history of fewer than three SBMs per week for at least six months, as confirmed during a 14-day screening period. Efficacy parameters being measured in this long-term safety trial include the frequency of SBMs at every week and the changes in SBMs at every week.

---

In September 2008, Sucampo announced that lubiprostone met the primary endpoint of a statistically significant increase in mean change from baseline in SBM frequency after one week on treatment (p-value less than 0.0001) in a phase 2b trial in Japanese patients taking 24-mcg of lubiprostone twice daily versus placebo.

## **About Sucampo Pharmaceuticals**

Sucampo Pharmaceuticals, Inc., an international biopharmaceutical company based in Bethesda, Maryland, focuses on the development and commercialization of medicines based on prostanes. The therapeutic potential of prostanes, which are bio-lipids that occur naturally in the human body, 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 and currently Advisor, International Business Development.

Sucampo markets Amitiza® (lubiprostone) 24 mcg in the U.S. for chronic idiopathic constipation in adults and Amitiza 8 mcg in the U.S. to treat irritable bowel syndrome with constipation in adult women. Sucampo also is developing the drug for additional gastrointestinal disorders with large potential markets. In April 2009, Sucampo acquired U.S. and Canadian rights to Rescula®, an FDA-approved treatment for open-angle glaucoma and ocular hypertension. Sucampo plans to re-launch Rescula in 2010, and to develop it for additional ophthalmic indications. In addition, Sucampo has a robust pipeline of compounds with the potential to target underserved diseases affecting millions of patients worldwide. Sucampo Pharmaceuticals, Inc. has three wholly owned subsidiaries: Sucampo Pharma Europe, Ltd., located in the UK; Sucampo Pharma, Ltd., located in Japan; and, Sucampo Pharma Americas, Inc., located in Maryland. To learn more about Sucampo Pharmaceuticals and its products, visit [www.sucampo.com](http://www.sucampo.com).

Amitiza is a registered trademark of Sucampo Pharmaceuticals, Inc.

## **About AMITIZA (lubiprostone) for Chronic Idiopathic Constipation and Irritable Bowel Syndrome with Constipation in the U.S.**

In the U.S., AMITIZA (lubiprostone) is indicated for the treatment of Chronic Idiopathic Constipation (24 mcg twice daily) in adults and for Irritable Bowel Syndrome with Constipation (8 mcg twice daily) in women  $\geq 18$  years of age and older.

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, 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 distention (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, the most common adverse reactions (incidence >4%) were nausea (8% vs. 4%), diarrhea (7% vs. 4%), and abdominal pain (5% vs. 5%).

Please see complete Prescribing Information at [www.amitiza.com](http://www.amitiza.com).

### **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 potential trial results, the potential utility of Amitiza and Rescula to treat particular indications and expected data availability, trial commencement and regulatory 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, 2008 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.

### **CONTACT:**

Sucampo Pharmaceuticals, Inc.

Kate de Santis, 240-223-3834

[kdesantis@sucampo.com](mailto:kdesantis@sucampo.com)

or

Westwicke Partners

John Woolford, 410-213-0506

[john.woolford@westwicke.com](mailto:john.woolford@westwicke.com)