

SciClone Announces Topline Results From Phase 2 Clinical Trial of SCV-07 for Prevention of Oral Mucositis

Study Shows Signal of Delay to Onset of Severe OM in Higher Dose Group

FOSTER CITY, CA, Mar 30, 2010 (MARKETWIRE via COMTEX News Network) -- SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN) today announced topline results from the company's phase 2 clinical trial of SCV-07 for the prevention of severe oral mucositis (OM) (World Health Organization, WHO scale, grades 3 to 4) -- a painful, debilitating, and costly toxicity caused by chemoradiotherapy regimens used to treat head and neck cancer. This proof of concept study was intended to provide an estimate of SCV-07's treatment effect and guide further studies of SCV-07 in addressing this serious unmet medical need. Patients receiving the study's higher dose (0.1 mg/kg) of SCV-07 showed a trend towards delay to onset of severe OM, the study's primary endpoint. Patients in the low dose treatment arm (0.02 mg/kg) appeared to do worse than placebo, suggesting that the treatment effect is sensitive to dose. Additionally, SCV-07 was safe and well tolerated with no drug-related serious adverse events reported, indicating that there is potential to administer higher doses of SCV-07 in future clinical studies.

Additional data analysis showed a more pronounced clinical benefit for patients in the high dose treatment arm when evaluating the delay to onset of ulcerative OM (WHO scale, grades 2 to 4), an expanded measure of OM. In this analysis, the low dose treatment arm appeared similar or slightly better than placebo.

"We are encouraged that the trial provides an indication of a biological signal, in the high dose arm, for the pre-specified primary endpoint of the study," said Stephen T. Sonis, DMD, DMSc, Senior Physician, Brigham and Women's Hospital, Professor of Oral Medicine, Harvard School of Dental Medicine, and a leading expert in oral mucositis. "The finding that extends this signal to ulcerative OM is important, as ulceration is the major cause of the morbidity associated with OM."

Based on these study findings, SciClone intends to initiate discussions with the United States Food and Drug Administration regarding the design of a second phase 2 study of SCV-07 for the prevention of OM, which would involve higher doses. SciClone has also submitted a late-breaking abstract on results of this study for the 2010 American Society of Clinical Oncology Annual Meeting.

"We believe these findings support the concept that SCV-07 could provide a clinically meaningful benefit in the prevention of OM for patients with head and neck cancer being treated with chemoradiotherapy by stimulating the immune system through critical signaling pathways," said Israel Rios, MD., Chief Medical Officer and Senior Vice President of SciClone.

The phase 2 multicenter, randomized, double-blind, placebo-controlled, dose ranging proof of concept study was designed to assess the safety and tolerability of SCV-07 as well as provide an indication of efficacy in delaying the onset of severe OM, as assessed by the WHO scale, in patients receiving standard chemoradiation therapy for treatment of cancers of the head and neck. The study was not designed to demonstrate statistical significance and the results are not statistically significant. The study was conducted at 21 centers in the United States and included 59 patients. Patients received either placebo, SCV-07 at a dose of 0.02 mg/kg, or SCV-07 at the higher dose of 0.10 mg/kg. The treatment period was approximately seven weeks depending on the patient's prescribed radiation plan, with a follow-up visit approximately 30 days following the last day of radiation therapy.

About Oral Mucositis OM is a painful, debilitating and costly toxicity of many of the drug or radiation regimens used to treat cancer. OM is a condition in which the sensitive cells lining the mouth and throat are damaged by cancer treatments such as chemotherapy (with or without radiation) and become painful mouth sores. Severe OM has been reported to occur in about 50% of patients who receive chemoradiation for the prevention of cancers of head and neck (Sonis, Core Evidence, 2009). Importantly, radiation to the head and neck, especially when it includes the tissues of the mouth, pharynx and hypopharynx, results in significant ulcerative OM in greater than 90% of patients (Manas et al, Clinical Translational Oncology, 2009) and can compromise the patient's ability or willingness to accept a complete course of therapy. Symptoms can include painful ulcers in the mouth and throat, redness and swelling of the gums, dryness and overall soreness in the mouth, and difficulty eating, swallowing, talking and drinking. In addition to the symptoms of OM and its impact on quality of life and continued therapy, mucositis can cause adverse affects on a variety of other health and economic outcomes, such as a risk of serious infection, the need for parenteral nutrition and narcotic analgesia, and increased hospitalization and feeding-tube placement. The National Cancer Institute estimates that 400,000 patients in the U.S. suffer from OM during cancer therapy.

WHO OM Scale The WHO OM Scale is the standard, validated instrument used in clinical trials to measure OM.

Grade 0 = None Grade 1 = Erythema and soreness; No ulcers Grade 2 = Ulcers; Able to eat a solid diet Grade 3 = Ulcers; Requires a liquid diet Grade 4 = Ulcers; Not able to tolerate a solid or liquid diet; Requires IV or tube feeding.

About SCV-07 SCV-07 (gamma-D-glutamyl-L-tryptophan) is a small molecule which appears to stimulate the immune system through inhibition of STAT3 signaling and the resulting effects on T-helper 1 cells. SCV-07 has been shown to be efficacious in animal models of immune-sensitive diseases, including OM prevention, treatment of viral infections and cancers, and in the enhancement of response to vaccines.

Additionally, SciClone is currently running a multicenter, multidose, open label phase 2 clinical trial of SCV-07 as a monotherapy and in combination with ribavirin to treat patients infected with hepatitis C virus, who have relapsed after the last treatment. SCV-07 has shown a good safety profile in several early stage clinical trials in healthy volunteers and subjects with HCV infection at various doses. SciClone expects to provide initial results from this trial in the second half of 2010.

SCV-07 is protected by composition of matter patents as well as multiple method of treatment patents. SciClone has exclusive worldwide rights to SCV-07 outside of Russia, where the molecule has recently been approved for stimulation of depressed immune systems.

About SciClone SciClone Pharmaceuticals (NASDAQ: SCLN) is a profit-focused, global specialty pharmaceutical company with a substantial international business and a product portfolio of novel therapies for cancer and infectious diseases. SciClone is focused on continuing international sales growth, a cost-containing clinical development strategy, and overall expense management. ZADAXIN(R) (thymalfasin or thymosin alpha 1) is sold in over 30 countries for the treatment of hepatitis B (HBV) and hepatitis C (HCV), certain cancers and as a vaccine adjuvant. SciClone's development pipeline of drug candidates includes thymalfasin, in clinical studies as an enhancer of vaccines; thymalfasin for stage IV melanoma, for which SciClone has reached agreement with the FDA on the design of a phase 3 trial; SCV-07, in clinical studies for the delay to onset of severe OM in patients receiving chemoradiation therapy for the treatment of cancers of the head and neck; and SCV-07 in a phase 2 trial for the treatment of HCV. SciClone has exclusive commercialization and distribution rights to DC Bead(TM) in China, where the product is under regulatory review. The Company also has exclusive commercialization and distribution rights to the anti-nausea drug ondansetron RapidFilm(TM) in China and Vietnam, for which it will seek regulatory approval. For additional information, please visit www.sciclone.com.

Forward-Looking Statements This press release contains forward-looking statements regarding development objectives and timing expectations. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "might," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. These statements are subject to risks and uncertainties that are difficult to predict and actual outcomes may differ materially. These risks and uncertainties include our ability to commence, and if commenced, complete clinical trials of SCV-07 and for such trials to demonstrate SCV-07 having a significant therapeutic effect for treatment of OM without adverse side effects. Please also refer to other risks and uncertainties described in SciClone's filings with the SEC. All forward-looking statements are based on information currently available to SciClone and SciClone assumes no obligation to update any such forward-looking statements.

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