SciClone
Pharmaceuticals

# SciClone Identifies Unique Genetic Markers Associated With Patient Response to SCV-07 Treatment in Oral Mucositis

## New Data From Phase 2a Oral Mucositis Study Presented at American Association for Cancer Research Conference

FOSTER CITY, CA, Sep 29, 2010 (MARKETWIRE via COMTEX News Network) -- SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN) today announced that researchers have identified two unique gene clusters that differentiated subjects who responded to treatment in the Company's phase 2a proof of concept study of SCV-07 for the prevention of severe oral mucositis (OM; WHO grades 3-4) in patients with advanced head and neck cancer. The Company believes that the discovery of these gene clusters may assist in providing the framework for effectively identifying those patients most likely to respond to SCV-07 in future clinical trials based on their individual genomic profile or gene signature. These findings were presented today in a poster presentation at the 4th American Association for Cancer Research (AACR) International Conference on Molecular Diagnostics in Cancer Therapeutic Development.

As part of the Company's recently completed phase 2a OM study, researchers collected and analyzed RNA samples from patients prior to and at the completion of the trial's treatment phase. Results from this gene expression analysis demonstrated the strong association of two specific gene clusters with patient response to SCV-07. Consistent with SCV-07's activity as a modulator of the immune system, these clusters included genes associated with G-protein coupled receptors, signal transducers, glycoproteins and membrane proteins.

"The identification of these specific genetic markers represents an exciting and potentially powerful development in the clinical advancement of SCV-07 for the treatment of oral mucositis," said Dr. Stephen T. Sonis, speaking in his role as Chief Medical Officer of Biomodels, LLC. Dr. Sonis is also a Clinical Professor of Oral Medicine at Harvard University, and a senior surgeon at Brigham and Women's Hospital and the Dana Farber Cancer Institute. "The previously reported findings from SciClone's phase 2a study suggested a consistent trend favoring patients in the trial's high dose group, and we now also have potentially critical insight into why this compound may be more likely to produce a response in a particular subset of patients. These new biomarker data should prove valuable in our ongoing research related to SCV-07 and we plan to further investigate this genomic profile and its connection to potential responders in future studies."

In addition to the gene expression differences, researchers demonstrated that SCV-07 treatment was associated with significant differences in levels of several immune-related cytokines thought to be important in the development of OM. Samples from patients treated with high dose SCV-07 were analyzed, and it was determined that levels of MIF ($p < 0.049$), MIP-1 beta ($p < 0.049$) and VEGF ($p < 0.015$) were found to be significantly higher compared to placebo, whereas levels of IL-1 alpha ($p < 0.045$) were found to be significantly lower compared to placebo. The patients in the low dose group did not demonstrate these same changes, consistent with the dose effects seen in the clinical study in which the lower dose did not show the same positive response seen in the higher dose treatment arm. The Company believes that the new information regarding cytokine activity may provide additional insight into the fundamental mechanism of action of SCV-07 in the treatment of OM.

"This phase 2a proof of concept study has provided significant clinical data to support the safety and potential efficacy of SCV-07, as well as the increasingly important area of biomarker identification," commented Friedhelm Blobel, Ph.D., SciClone's President and Chief Executive Officer. "Importantly, each of these findings will inform our ongoing clinical development of SCV-07 and we look forward to initiating our phase 2b study in patients with OM in late 2010 or early 2011."

On May 17, 2010, SciClone announced topline results from the Company's phase 2a proof of concept study of SCV-07 for the prevention of severe OM in patients with advanced head and neck cancer.

Based on the findings from the phase 2a study and completed discussions with the U.S. Food and Drug Administration, SciClone is planning to initiate a phase 2b study in late 2010 or early 2011. As compared to the completed phase 2a trial, the phase 2b study design is expected to include higher doses of SCV-07 and be adequately powered to demonstrate statistical significance. Additionally, researchers will continue to investigate the role of specific genetic profiles on patient response to SCV-07, as well as the potential link between cytokine activity and SCV-07's sub-cellular mechanism of action.

About Oral Mucositis OM is a common, painful, debilitating complication of cancer treatment, and SciClone estimates that total medical costs may reach around $4.2 billion in the U.S. and $10 billion worldwide in 2010. 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 effects 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.

About SciClone SciClone Pharmaceuticals (NASDAQ: SCLN) is a profit-focused, China-centric specialty pharmaceutical company with a substantial international business and a product portfolio of novel therapies for cancer and infectious diseases. The Company is focused on continuing sales growth, particularly in China, and a clinical development strategy with prudently managed costs. 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. In addition to further studying thymalfasin's use as a vaccine enhancer, SciClone is planning to evaluate SCV-07 in a phase 2b trial to modify the course of oral mucositis in patients with head and neck cancer; and is evaluating SCV-07 in a phase 2b trial for the treatment of HCV. The Company also has exclusive commercialization and distribution rights in China to a novel treatment for advanced liver cancer, DC Bead(R), currently under review by Chinese regulatory agencies. Additionally, SciClone owns exclusive commercialization and distribution rights to the anti-nausea drug ondansetron RapidFilm(TM) in China, including Hong Kong and Macau, and Vietnam. The Company will seek regulatory approval for the product, commonly used to treat and prevent nausea and vomiting caused by chemotherapy, radiotherapy, and surgery, in each of these markets. For additional information, please visit www.sciclone.com.

DC Bead is a registered trademark of Biocompatibles UK Limited.

RapidFilm is a trademark of Labtec Gesellschaft fuer technologische Forschung und Entwicklung mbH.

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," "potential," "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 whether we are able to initiate the phase 2 trial and, if commenced, complete clinical trial of SCV-07 and whether such trial demonstrates 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.

SOURCE: SciClone Pharmaceuticals, Inc.