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SciClone Announces Progress In Advancing Clinical Pipeline For China Pharmaceuticals Market

First Patient Treated in ZADAXIN® Phase 3 Sepsis Trial, Key to Expanding Market Penetration for Flagship Product;
First Patient Treated in Phase 1 Proof-of-Concept Trial of PT-112, Valuable New Asset to Drive Oncology Portfolio Growth

FOSTER CITY, Calif., Sept. 26, 2016 /PRNewswire/ -- SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN) today announced two important achievements in advancing the Company's clinical pipeline and development portfolio in Greater China. The first patient has been treated in the Phase 3 trial of ZADAXIN® in sepsis, a life-threatening infectious disease in which the drug has previously demonstrated therapeutic benefit in a Phase 2 clinical trial. The sepsis trial is a major component of SciClone's strategy to grow ZADAXIN sales in the indications for which it is approved, as well as new indications. In addition, the first patient has been treated in the Phase 1 trial of PT-112, a multi-targeted platinum-pyrophosphate anticancer agent being developed for patients with advanced solid tumors. PT-112 is a key early-stage asset supporting SciClone's strategy to expand its oncology portfolio and drive long-term growth.

Friedhelm Blobel, PhD, SciClone's President and Chief Executive Officer, commented: "In different ways, both of these clinical development programs represent essential strategies to ensure SciClone's continued growth over the near and long term. ZADAXIN is our flagship product, and the leading branded thymalfasin on the market in China. We believe that it continues to have significant growth potential, and our sepsis initiative will be key to expanding its market leadership. As we have noted previously, we are hopeful that with a positive outcome in the Phase 3 trial, ZADAXIN could be actively recommended in the China Sepsis Treatment guideline for sepsis treatment, potentially expanding utilization and continuing ZADAXIN's strong growth momentum."

Continued Dr. Blobel: "PT-112 is a valuable addition to our development portfolio, with the potential to meaningfully expand our oncology business in China for the future. Given the poor prognosis of patients with refractory and/or recurrent platinum-resistant advanced cancer, the opportunity to develop a treatment for patients in Greater China with a therapeutic agent that combines tolerability with mechanistic differentiation is highly desirable. PT-112 also provides us with the opportunity to leverage the Class 1 regulatory pathway, offering the potential for local manufacturing and other advantages that could accelerate development and registration in China."

Phase 3 Trial in Sepsis Has Potential to Expand ZADAXIN Market Leadership

The goal of the SciClone-sponsored Phase 3 trial in sepsis is to build on positive data from a smaller, previously conducted trial which showed a survival advantage for sepsis patients treated with ZADAXIN. The 1,104-patient Phase 3 trial is being led by Professor Guan of Sun Yat-Sen University in Guangdong, a highly respected sepsis expert. The Phase 3 trial is designed to generate data confirmatory of ZADAXIN's effectiveness in treating sepsis. Patients will be dosed with 3.2 mg per day for one week. The primary end point is the 28-day mortality rate, with secondary endpoints, including measurement of immunomodulatory parameters. SciClone anticipates completing enrollment in the Phase 3 trial in 2018, with data potentially available in 2019. A positive outcome in this Phase 3 trial could lead to inclusion of ZADAXIN in the China Sepsis Treatment Guidelines.

Sepsis in China represents a major unmet medical need, affecting more than four million patients and with a mortality rate over 20%. The potential therapeutic utility of immunomodulatory therapy to reduce the high mortality of sepsis has been explored in earlier trials in China and other markets, and has shown evidence of increasing immune system functionality and immune parameters in patients with sepsis.

PT-112 Has First-in-Class Potential

It is estimated that up to 80% of cancer patients are prescribed platinum-containing regimens (cisplatin, carboplatin, oxaliplatin) at some point during their treatment. The adverse effects of this class of chemotherapeutics, including renal and neurotoxicity, have limited their use.

PT-112 is a novel chemical entity and represents a potential first-in-class platinum-containing compound. It was rationally designed to solve issues of toxicity while providing enhanced therapeutic benefit and minimizing dependency on DNA repair-based drug resistance historically associated with the therapeutic class. SciClone obtained exclusive development and commercialization rights to PT-112 from Phosplatin Therapeutics for Greater China and Vietnam, along with option rights in South Korea and Taiwan.

The recently initiated Phase 1 study of PT-112 is being conducted in Taiwan. The dose-escalation portion of the trial, which is expected to complete enrollment in early 2017, includes subjects with current solid tumors treated initially with 50 mg/m2. This will be followed by a dose-confirmation phase, including a specific population of NSCLC patients. In addition, manufacturing of PT-112 has been initiated in China and is expected to be ready in time for submission of an Investigational New Drug (IND) application in China in 2017.

In non-clinical studies, PT-112 has been shown to be highly active, including in resistant cell lines and animal models, with less neurotoxicity and renal toxicity, better pharmacokinetic stability and higher levels of tolerability. *In vitro* studies have demonstrated synergistic activity using different cell lines, including non-small cell lung cancer. Phosplatin Therapeutics is currently conducting a first-in-human Phase 1 clinical study of PT-112 in patients with advanced solid tumors at several sites in the US, led by the MD Anderson Cancer Center. Results thus far have shown tolerability, pharmacokinetic stability and signals of clinical benefit and biological activity with no overlapping toxicities when compared with docetaxel.

About SciClone

SciClone Pharmaceuticals is a revenue-generating, specialty pharmaceutical company with a substantial commercial business in China and a product portfolio spanning major therapeutic markets including oncology, infectious diseases and cardiovascular disorders. SciClone's proprietary lead product, ZADAXIN® (thymalfasin), is approved in over 30 countries and may be used for the treatment of hepatitis B (HBV), hepatitis C (HCV), and certain cancers, and as an immune system enhancer, according to the local regulatory approvals. The Company has successfully in-licensed and commercialized products with the potential to become future market leaders and to drive the Company's long-term growth, including DC Bead®, a novel treatment for liver cancer now approved in China, and several other products in late stage development in China. Through its promotion business with pharmaceutical partners, SciClone also markets multiple branded products in China which are therapeutically differentiated. SciClone is a publicly-held corporation based in Foster City, California, and trades on the NASDAQ Global Select Market under the symbol SCLN. For additional information, please visit www.sciclone.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding expected future events and SciClone's expectations, including but not limited to the therapeutic potential and expected development and regulatory timelines for ZADAXIN in sepsis and PT-112 in cancer. Readers are urged to consider statements that include the words "may," "will," "would," "could," "should," "might," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "designed," "goal," "approximately" 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. 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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