

SAMUMED PRESENTS DATA FOR POTENTIAL TOPICAL TREATMENT FOR PSORIASIS

Plans to initiate clinical study in 2017

San Diego, CA—November 16, 2016 – Samumed presented at the 2016 American College of Rheumatology (ACR) Annual Meeting preclinical results from *in vitro* and *in vivo* studies regarding the use of its small molecule compound SM04755 as a potential topical treatment for psoriasis. SM04755 is one of two small molecule Wnt pathway modulators (together with SM04690 which is in clinical trials for osteoarthritis and degenerative disc disease) for which Samumed has presented clinical and/or preclinical data across five different rheumatic diseases.

Psoriasis is an autoimmune disease of the skin, characterized by inflammation and fibrosis, producing patches of red, itchy and scaly skin. (Dees C and Distler JH. *Exp Dermatol.* 2013;22(11):710-3.) From *in vitro* studies, SM04755 inhibited inflammation, keratinocyte proliferation, and fibrosis. In an *in vivo* mouse model, topically applied SM04755 inhibited inflammation, cell proliferation, and decreased skin thickness compared to vehicle. These studies demonstrated that SM04755 has potential as a topical therapy for psoriasis.

Samumed presented, inter alia, the following images related to its *in vivo* study as part of its presentation at ACR on this potential treatment for psoriasis:



Images of skin (top panel) and ears (bottom panel) from (i) imiquimod (IMQ) and vehicle-treated or (ii) IMQ and SM04755 (0.2 mg/cm²)-treated mice on day 20

“Based on our study results, we are excited about SM04755’s potential as a treatment for psoriasis. Treatment of mild to moderate psoriasis using a safe and effective topical agent remains an area of intense medical research,” said Yusuf Yazici, M.D., Chief Medical Officer of Samumed. “Our Phase 1 trial for chronic tendinopathy using the same topical investigational drug will form the basis to expand into a Phase 2 study for psoriasis in 2017.”

From *in vitro* studies, anti-inflammatory activity was evaluated by measuring IL-6 and TNF- α secretion using ELISA in Lipopolysaccharides-stimulated THP-1 monocytes and anti-CD3/anti-CD28-stimulated peripheral blood mononuclear cells. Cytokine-induced keratinocyte proliferation was measured in primary human keratinocytes using an EdU incorporation assay. Finally, the effect on fibrosis was assessed in TGF- β 1-stimulated human dermal fibroblasts by measuring smooth muscle actin, plasminogen activator inhibitor, connective tissue growth factor, and collagen expression by qPCR.

In vivo efficacy was evaluated in an imiquimod (IMQ)-induced mouse psoriasis model with daily topical IMQ (0.3mg/cm²) application on the back and ear for 20 days, along with daily treatment with topical SM04755 starting on day 3 after the first IMQ application. Efficacy was assessed by measurement of skin and ear thickness, spleen size and weight, cytokine levels in plasma, and histological measurements of inflammation. Dermal and epidermal thickness were assessed by hematoxylin & eosin staining and proliferation in the skin using bromodeoxyuridine labeling.

The abstract for the presentation is available at ACR’s website here: [Discovery of a Small Molecule Inhibitor of the Wnt Pathway \(SM04755\) As a Potential Topical Treatment for Psoriasis](#). The poster presented at this session, which includes the details of methodologies and results, is available [here](#).

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ABOUT SAMUMED, LLC

Based in San Diego, CA, Samumed (www.samumed.com) is a pharmaceutical platform company focused on advancing regenerative medicine and oncology applications through research and innovation. Samumed has discovered new targets and biological processes in the Wnt pathway, allowing the team to develop small molecule drugs that potentially address numerous degenerative conditions as well as many forms of cancer.