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SAMUMED BEGINS ENROLLMENT IN A PHASE II CLINICAL TRIAL FOR THE TREATMENT OF OSTEOARTHRITIS (OA) OF THE KNEE USING A NOVEL WNT PATHWAY MODULATOR

SAN DIEGO—November 6, 2015—Samumed, LLC, a leader in tissue regeneration, announced today that it has started enrolling patients in a Phase II, multicenter, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, and efficacy of SM04690 injected in the target knee joint of moderately to severely symptomatic OA patients. The investigational drug SM04690 is a small molecule inhibitor of the Wnt pathway.

The approximately 400-patient trial will study three different doses of SM04690 against a placebo, with 100 patients in each arm. The primary outcome measures for the study are change from baseline as assessed by Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and function subscores at Week 13, as well as patient global assessment during the same time period. The WOMAC is a widely-used, proprietary outcome measurement tool used to evaluate the condition of patients with OA of the knee and hip, including pain, stiffness, and physical function of the joints.

In addition, the trial will study change from baseline in joint space width (i.e., the distance between the two bones in the target knee) as documented by radiographs (x-ray) of the target knee at Weeks 26 and 52. “Both the safety and the efficacy results of our Phase I trial encouraged us to move into a Phase II clinical trial,” said Yusuf Yazici, M.D., Chief Medical Officer of Samumed.

At the Annual Meeting of the American College of Rheumatology next week, the company will present preclinical results demonstrating cartilage regeneration in an animal model of OA. Additionally, safety, pharmacokinetics, efficacy, and imaging results (MRI and radiographs) from the completed 24-week placebo-controlled, double-blind, randomized Phase I clinical trial of SM04690 in patients with moderate to severe osteoarthritis of the knee will be presented.

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.

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