



PRESS RELEASE

Samumed Announces Positive End-of-Phase 2 Meeting with FDA for SM04690 in Knee Osteoarthritis

STRIDES Phase 3 studies to commence first half of 2019

SAN DIEGO – February 28, 2019 – Samumed, LLC, announced today that it has successfully completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding the approval path for SM04690, a small-molecule inhibitor of the Wnt pathway, for knee osteoarthritis (OA).

“Our collaborative interactions with the FDA help solidify SM04690 as a Phase 3-ready drug candidate with a clear path to approval. With this Agency input, we remain on track to initiate pivotal studies the first half of this year,” said Dr. Yusuf Yazici, Chief Medical Officer of Samumed.

The first Phase 3 study, STRIDES X-ray, will investigate the effects of SM04690 on the Daily Pain Numerical Rating Scale (NRS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Function subscore, while also assessing potential disease modification through changes in medial joint space width as measured by x-ray over 12 months. Another Phase 3 study, STRIDES 1, a six-month trial, will evaluate the primary endpoint of pain as measured by NRS and a key secondary endpoint of function as measured by the WOMAC subscale versus placebo.

“We are excited to initiate our planned Phase 3 program for SM04690 to demonstrate its potential benefits on pain, function and structural progression,” commented Osman Kibar, CEO of Samumed.

This End-of-Phase 2 meeting followed the successful completion of a 24-week Phase 2b trial, designed to evaluate SM04690 versus placebo in 700 patients with moderate to severe knee OA. Results showed that treatment with a single intraarticular injection of SM04690 produced significant improvements in pain, function, and patient global assessment scores compared to placebo control. In a previous, 450-subject Phase 2a study, Samumed demonstrated significant improvement in medial joint space width compared to placebo, consistent with potential structural benefit, in a pre-specified, clinically relevant subgroup.

About Osteoarthritis

Arthritis is the leading cause of adult disability. As the most common type of arthritis, osteoarthritis (OA) is characterized by the destruction of articular cartilage and structural changes in bone, which contribute to pain and loss of joint function. An estimated 30 million U.S. adults suffer from OA, primarily due to an aging population and an increasing prevalence of obesity. The combination of direct medical costs, pain and suffering, and loss of workplace

samumed

productivity elevates OA to a major socioeconomic problem for health systems, the economy, and suffering patients. Current treatment options for patients are palliative in nature with no approved disease-modifying agents available to patients.

About SM04690

SM04690 is a small-molecule inhibitor of the Wnt pathway administered as an intra-articular injection and is in development as a potential disease-modifying drug for osteoarthritis (DMOAD). Vehicle-controlled preclinical data suggested that SM04690 has a dual mechanism of action with three effects on joint health – generation of cartilage, slowing down of cartilage breakdown, and reduction of inflammation. There are currently no approved disease-modifying treatments for osteoarthritis. Additional information on Samumed’s SM04690 osteoarthritis program can be found here: <https://www.samumed.com/pipeline/detail.aspx?id=20>.

About Samumed

Samumed’s small-molecule drug platform is harnessing the innate restorative power of the Wnt pathway to reverse the course of severe and prevalent diseases. Learn more about Samumed’s potential regenerative drug candidates and broad clinical pipeline at <https://www.samumed.com/pipeline/default.aspx>.

Corporate Contact:

Erich Horsley
Samumed, LLC
erich@samumed.com
858-365-0200

Investor Contact:

Ashley Robinson
LifeSci Advisors
arr@lifesciadvisors.com
617-535-7742

Media Contact:

Josephine Belluardo, Ph.D.
LifeSci Public Relations
jo@lifescipublicrelations.com
646-751-4361