



PRESS RELEASE

Samumed Launches Phase 3 Lorecivivint (SM04690) Clinical Program in Knee Osteoarthritis

Pivotal STRIDES trials to be conducted to support lorecivivint as a potential disease-modifying treatment for knee osteoarthritis

First patient dosing is anticipated in the second quarter of 2019

SAN DIEGO – May 2, 2019 - Samumed, LLC, announced today that it has finalized the design of its phase 3 clinical program of lorecivivint (SM04690) for the treatment of knee osteoarthritis (OA), which will consist of pivotal trials studying the effects of lorecivivint on patient-reported outcomes and disease progression. The pivotal program will be referred to as STRIDES (SM04690 Trial Evaluating a Randomized Injection for Determination of Efficacy and Safety).

“Our phase 2 lorecivivint studies showed improvements in pain, function, and medial joint space width—a measure of structural disease progression—in patients with clinically-relevant knee OA, and supported the initiation of phase 3 trials. The comprehensive phase 3 plan is designed to evaluate the potential of lorecivivint to safely provide relief from symptoms and modify the course of disease for people currently suffering from knee OA,” said Mark Fineman, Ph.D., Senior Vice President, Clinical Development of Samumed.

“We recently completed the investigator meeting for STRIDES X-ray and anticipate enrolling our first subjects in the near future. Initiating this trial represents a major milestone for lorecivivint, Samumed, and potentially for the millions of patients with OA of the knee. We look forward to providing further updates on this study, as well as the additional STRIDES trials, throughout 2019,” added Yusuf Yazici, M.D., Chief Medical Officer of Samumed.

The lorecivivint phase 3 clinical program will begin with the initiation of the STRIDES X-ray trial, a 56-week study evaluating the efficacy and safety of a single intra-articular injection of 0.07 mg lorecivivint to reduce pain in the target knee. The trial is expected to enroll about 725 patients across 70 sites in the U.S. The main endpoints will include reduction in pain as measured by the Pain Numeric Rating Scale, improvements in function as measured by Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and knee medial joint space width as measured by X-ray.

Erich Horsley, Chief Business Officer of Samumed, added, “We look forward to completing our phase 3 program that will establish lorecivivint as a transformative treatment for knee OA. With over 10 million patients in the US, knee OA has a significant impact to society in terms of patient suffering, comorbid conditions, and lost workplace productivity. An approved, safe therapy that addresses both symptoms and has structural benefit would dramatically transform the treatment landscape for this serious condition.”

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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 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.

About Lorecivivint

Lorecivivint (SM04690) is a small-molecule inhibitor of the Wnt pathway that is administered as an intra-articular injection and is in development as a potential disease-modifying drug for osteoarthritis (DMOAD). Vehicle-controlled preclinical data suggest that lorecivivint has a dual mechanism of action with three effects on joint health – generation of cartilage, slowing of cartilage breakdown, and reduction of inflammation. There are currently no approved disease-modifying treatments for osteoarthritis. Additional information on Samumed's lorecivivint 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>

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