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PRESS RELEASE

Samumed Doses First Subject in Phase 3 STRIDES-X-ray Trial of Lorecivivint for the Treatment of Knee Osteoarthritis

The study will measure clinical and structural effects to assess the disease-modifying capabilities of lorecivivint

SAN DIEGO – June 19, 2019 - Samumed, LLC, announced today that it has dosed the first patient in its Phase 3 STRIDES-X-ray trial of lorecivivint (SM04690), a CLK/DYRK inhibitor that modulates the Wnt pathway, in patients with knee osteoarthritis (OA). The trial is designed to support the development of lorecivivint as a potential disease-modifying osteoarthritis drug (DMOAD).

"A drug candidate must show both clinical and structural benefit for it to be a disease-modifying drug for OA. We have designed the STRIDES-X-ray trial to investigate lorecivivint in these two key areas over one year," said Yusuf Yazici, M.D., Chief Medical Officer of Samumed. "In previous studies, lorecivivint improved joint structure as measured by X-ray in a clinically relevant and prespecified subgroup of patients. Our STRIDES-X-ray trial aims to build upon these prior positive data to confirm that lorecivivint can modify the course of OA."

The STRIDES-X-ray trial (NCT03928184) is a Phase 3, 56-week, multicenter, randomized, double-blind, placebo-controlled study utilizing patient-reported pain and function endpoints and radiographic outcomes to evaluate the efficacy and safety of a single intra-articular injection of 0.07 mg lorecivivint in patients with moderate-to-severe knee OA. The trial is expected to enroll about 725 patients across 70 sites in the U.S. Select key endpoints will include change in pain as measured by the Pain Numeric Rating Scale (NRS), change in function as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and change in knee medial joint space width as measured by X-ray.

Samumed has designed a comprehensive Phase 3 clinical program consisting of multiple pivotal trials evaluating the effects of lorecivivint on patient-reported outcomes and OA disease structural progression. These trials are intended to support an eventual New Drug Application and the potential approval of lorecivivint as a treatment for osteoarthritis.

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 to patients.

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About Lorecivivint
Lorecivivint (SM04690) is a small-molecule CLK/DYRK inhibitor that modulates the Wnt pathway 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. Currently, there are 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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