



PRESS RELEASE

Samumed Presents Safety Data Analysis of Lorecivint for Knee Osteoarthritis at the 2019 ACR Annual Meeting

Data showed that lorecivint had a safety profile similar to placebo

The Company previously presented data from Phase 2 trials demonstrating sustained pain and function improvements out to 24 and 52 weeks

SAN DIEGO – Nov. 13, 2019 – Samumed, LLC, presented a new clinical safety analysis of lorecivint, a CLK/DYRK1A inhibitor that modulates the Wnt pathway, in a poster presentation at the 2019 American College of Rheumatology (ACR) Annual Meeting. Lorecivint appeared safe and well tolerated in the pooled analysis of three randomized controlled trials that evaluated a single intra-articular (IA) injection in subjects with knee osteoarthritis (OA).

“Recent concerns over the safety of current OA treatments highlight the need for new therapies with more favorable safety profiles,” said Yusuf Yazici, M.D., Chief Medical Officer of Samumed. “To evaluate the safety of lorecivint, we pooled the safety data from more than 1,200 subjects who have participated in our clinical studies to date. These data showed that this potential new therapy was well tolerated and appeared safe. We look forward to continuing our Phase 3 clinical program, which we have designed to establish lorecivint as a potentially disease-modifying drug for knee OA.”

Samumed analyzed the data from all 1,208 subjects across its Phase 1 and Phase 2 trials that investigated lorecivint for moderate to severe symptomatic knee OA. This pooled safety data showed that the overall incidence of adverse events (AEs) was 41.3% for the 848 lorecivint-treated subjects and 38.3% for the 360 control subjects. Incidence of serious adverse events (SAEs; 2.4% treated, 1.1% control) was low; all SAEs were deemed unrelated to lorecivint by investigators. The only AE reported at greater than 5% in either subject group was arthralgia, or joint pain (treated 7.8%, control 7.2%). In all AE categories, including those related to bone health, individual AEs were reported at comparable rates between the treated and control groups. Samumed continues to evaluate the safety profile of lorecivint through multiple long-term safety trials.

Samumed presented data in three additional presentations, one oral and two posters, at the 2019 ACR Annual Meeting. The Company also hosted an Innovation Theater on lorecivint’s novel approach to knee OA. A copy of all oral and poster presentation materials can be found in the [Publications](#) section of the Samumed website.

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About the American College of Rheumatology (ACR) Annual Meeting

The American College of Rheumatology Annual Meeting hosts close to 16,000 rheumatologists, rheumatology health professionals, fellows-in-training, and exhibitors from more than 100 countries to experience the latest scientific advances, clinical issues, professional development, and more in the field of rheumatology.

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. Currently, there are no approved disease-modifying treatments for osteoarthritis.

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. 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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