



PRESS RELEASE

Samumed Announces Multiple Presentations at the 19th World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases

Poster with new data from a recently completed phase 2b trial of SM04690 for the treatment of knee osteoarthritis highlights the effects of saline placebo injections versus sham injections

SAN DIEGO – April 10, 2019 - Samumed, LLC, announced today that it presented new clinical data from its phase 2b trial of a novel small-molecule Wnt pathway inhibitor, SM04690, which is in development as a potential disease-modifying drug for the treatment of knee osteoarthritis (OA) at the 19th World Congress on Osteoporosis, Osteoarthritis, and Musculoskeletal Diseases (WCO), held from April 4th-7th, 2019, in Paris, France. The poster presentation compared the effects of placebo saline knee injections versus sham injections.

“We are excited to have presented, for the first time, data from our phase 2b knee osteoarthritis trial which compares the efficacy of saline placebo injections versus sham injections. We believe that these data, which suggest that the improvements we observed in the saline placebo arm were contextual and not due to a therapeutic benefit of the injected saline, will be useful for the medical and drug development community to inform future clinical trial designs utilizing intra-articular injections,” said Yusuf Yazici, M.D., Chief Medical Officer of Samumed. “Following positive results from our phase 2b trial of SM04690 for the treatment of knee OA, we look forward to further contributing to both the current knowledge about knee OA as well as advancing this promising product candidate through the clinic in our upcoming phase 3 STRIDES trials beginning in the coming months.”

Samumed’s phase 2b trial of SM04690 for the treatment of knee OA was a 700-patient, 24-week, multicenter, randomized, double-blind, placebo-controlled study. An analysis of 207 subjects from this trial demonstrated that subjects receiving a saline placebo injection or a sham intra-articular injection showed clinically relevant improvements (>10%) from baseline in multiple patient-reported pain and function outcome measures. These improvements were observed at the first post-baseline measurement and persisted through Week 24. No clinically meaningful or statistically significant differences were evident between the two groups at any time point. These results suggest that the patient-reported benefits from the saline placebo injections were due to a true placebo effect resulting from the injection procedure rather than from direct therapeutic effects of saline in the joint.

Samumed also delivered an oral presentation highlighting positive results from its SM04690 phase 2b trial as well as an additional poster presentation detailing previously reported findings on SM04690’s mechanism of action involving novel Wnt pathway targets. Further details can be found on the WCO website at <https://www.wco-iof-esceo.org/>. A copy of the presentation materials can be accessed by visiting the [Publications](#) section of the Samumed website.

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About the 19th World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (WCO)

For the 19th WCO conference, members of the Committee of Scientific Advisors of the International Osteoporosis Foundation (IOF) and the Scientific Advisory Board of the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) developed a program to bring together the world's best in the field of musculoskeletal health and disease. The Congress aims to move the field one step forward on all fronts: from new understanding of bone metabolism and pathology, to new strategies and options in prevention, diagnosis, and treatment.

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.

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 suggest 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. Currently, there are 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>.

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