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Samumed Announces Results of Phase 2 Trial of SM04690 Demonstrating Evidence of Cartilage Regeneration in Patients with Knee Osteoarthritis

- Data support potential of SM04690 as a disease modifying drug for knee osteoarthritis –

SAN DIEGO – Nov. 6, 2017 – Samumed, LLC, today announced detailed results from the Phase 2 proof-of-concept study of SM04690, a small molecule Wnt pathway inhibitor, in patients with osteoarthritis (OA) of the knee, at the 2017 American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) Annual Meeting. In a pre-specified subpopulation of patients with unilateral symptomatic knee OA, following a single intra-articular injection of SM04690, study results showed an increase in medial compartment joint space width (mJSW) at 52 weeks, as measured by x-ray of the knee, as well as improvements in pain and function scores.

“The disease modifying potential of SM04690 and the correlation of structural improvements with signs and symptoms improvements are very promising developments for the osteoarthritis community,” said Yusuf Yazici, M.D., Chief Medical Officer of Samumed.

In this proof-of-concept study, subjects with moderately to severely symptomatic knee OA were administered a single injection into the more painful (target) knee. Patients were evaluated for changes in pain and function using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and function scores. Analyses were conducted in two pre-specified populations: (1) the intent-to-treat (ITT) population comprised of all randomized subjects (N=455); and (2) a subgroup of unilateral symptomatic knee OA subjects (n=164). The subpopulation of unilaterally symptomatic patients was prespecified based on the hypothesis that patients with OA in both knees receiving treatment in only one knee may not respond as well as unilaterally symptomatic patients being treated in the only symptomatic knee due to various clinical factors, including mechanical off-loading to the treated knee, or diffusion of sense of pain from the untreated joint.

In unilateral symptomatic subjects treated with 0.07 mg of SM04690, both patient-reported outcomes, as well as objective measures of structural progression as measured by x-ray, showed statistically significant improvements. Clinically meaningful and significant improvements from baseline vs. vehicle were observed in WOMAC Pain (P=0.049 at Week 52), WOMAC Function (P=0.035 at Week 52) and mJSW (P= 0.006 at Week 26 and P=0.021 at Week 52). In an additional post-hoc analysis, improvements in the objective x-ray measures for these patients were concordant with improvements in their patient reported outcomes. Collectively, these data demonstrate the potential of SM04690 as the first disease modifying drug for knee osteoarthritis (DMOAD).

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"We are particularly encouraged by the finding that positive changes in objective structural observations per x-ray results were corroborated by similar signs and symptoms relief as reported by the patients," added Dr. Yazici. "Our Phase 2b trial is currently enrolling with data expected in mid-2018."

In the ITT population, clinically meaningful improvements vs. baseline in WOMAC Pain and WOMAC Function were observed for all subjects at all time points. However, these positive trends did not show statistically significant differences. The safety profile of SM04690 was similar to vehicle with no drug-related serious adverse events reported in the study.

The oral presentation slides with full study results can be viewed at https://www.samumed.com/medium/image/american-college-of-rheumatology-acr-11032017_225/view.aspx, and the associated abstract can be viewed at https://www.samumed.com/medium/image/american-college-of-rheumatology-11052017_220/view.aspx.

About SM04690

SM04690 is a small molecule inhibitor of the Wnt pathway administered as an intra-articular injection, and is being developed as a potential disease modifying drug for osteoarthritis (DMOAD). Preclinical data suggest SM04690 has a dual mechanism of action with three specific effects on joint health – generating new articular cartilage, slowing down cartilage degradation, and reducing inflammation in the joint. 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. Samumed's clinical pipeline can be found here: https://www.samumed.com/pipeline/default.aspx

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