

PRESS RELEASE

Samumed Doses First Patient in Phase 1 Trial of SM04690 for Treatment of Degenerative Disc Disease

SAN DIEGO – Dec. 18, 2017 – Samumed, LLC, today announced the dosing of the first degenerative disc disease (DDD) patient in its Phase 1 trial of SM04690, a small molecule Wnt pathway inhibitor formulated as an intradiscal injection.

Degenerative disc disease is a condition characterized by age-related changes to the intervertebral discs, which become less able to act as a shock absorber in the spine. Recent studies have shown that over-active Wnt signaling may be involved in the disease processes of DDD. Preclinical studies with SM04690 have demonstrated its ability to induce proliferation and differentiation of disc progenitor cells and regeneration of intervertebral disc structures.

“Current treatment options for patients with degenerative disc disease address the symptoms of the disease, but are unable to treat its underlying cause,” said Dr. Yusuf Yazici, Chief Medical Officer of Samumed. “By selectively modulating the Wnt pathway, we aim to address the cause of the disease to preserve disc integrity and potentially lead to disc regeneration in patients with DDD.”

This Phase 1 open-label study will evaluate the safety, tolerability and pharmacokinetics (PK) of SM04690 injectable suspension following single intradiscal injection in subjects with DDD. Three cohorts of subjects will receive a single intradiscal injection of 0.03 mg, 0.07 mg or 0.15 mg SM04690. The primary objectives of the Phase 1 study include safety and tolerability, incidence of dose limiting toxicities and PK measures. Exploratory objectives include evaluating the clinical efficacy of SM04690 for the treatment of DDD through the evaluation of intravertebral discs on MRI, lumbar pain assessment, overall disease and disability progression.

About Degenerative Disc Disease

Degenerative disc disease (DDD) is a condition characterized by age-related changes to the intervertebral discs, the gel-like cushions that separate vertebrae. Over time, these discs become less flexible and less able to cushion the spine. This can result in pain and stiffness in the neck and/or back, as well as pain that spreads to the back of the head, trunk, shoulders, arms, hands, legs, and feet. It is estimated that as many as 80 percent of all adults experience back pain at some point during their lifetime, the chief cause of which is DDD.

About SM04690

SM04690 is a small molecule, Wnt pathway inhibitor being developed for the treatment of DDD and knee osteoarthritis. Preclinical data show that in a rat model of DDD, a single intradiscal injection of SM04690 initiated regeneration, improved intervertebral disc structure, and improved disc health.



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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