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JVS-100: A non-viral gene therapy encoding stromal cell-derived factor-1 for treatment of ischemic cardiovascular disease

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Abstract

Stromal cell-derived factor-1 (SDF-1) has been shown to promote tissue repair following ischemic injury in multiple organ systems by promoting stem cell recruitment and vasculogenesis. JVS-100 is a non-viral DNA plasmid encoding human SDF-1 that expresses SDF-1 for ~20 days. JVS-100 is currently in clinical testing to treat heart failure (HF) and critical limb ischemia (CLI), two large unmet clinical needs that collectively affect over 8 million Americans. JVS-100 delivered to the heart via an endomyocardial injection catheter has demonstrated safety and clinical improvement in a Phase 1 open-label dose-escalation study. In 17 patients with symptomatic ischemic HF followed through 12 months, a single treatment of 5 mg, 15 mg or 30 mg via 15 injections showed a favorable safety profile with no serious adverse events clearly attributable to study drug. At 4 months post-injection, patients showed a dose-dependent, clinically significant improvement over baseline in quality of life scores, 6-minute walk distance, and NYHA class that was sustained to 12 months. Similarly, in a CLI preclinical toxicology/efficacy study where JVS-100 (4 or 8 mg) was delivered by direct intramuscular injections into the hind limb of CLI rabbits, at 30-60 days post-injection, a 40% improvement in vessel density was observed compared to placebo-injected controls with no significant safety findings. On the basis of these data, two randomized, placebo-controlled Phase II trials, STOP-CLI (n=48) and STOP-HF (n=90) to test the clinical efficacy of JVS-100 have been initiated with enrollment in each to be completed in the first half of 2013.

Biography

Joseph Pastore, Ph.D. is currently Vice President of Product Development at Juventas Therapeutics. He joined Juventas after working with Guidant Corporation (acquired by Boston Scientific) where he was responsible for translating novel cardiac therapies from concept to clinic. He managed pre-clinical, first-in-man, and Phase 2 clinical trials, and worked cross-functionally with business development, marketing, reimbursement and regulatory teams to build and execute development strategies for early stage products. He received his Ph.D. in Biomedical Engineering from Case Western Reserve University. An inventor on more than 60 issued and pending patents, he has experience with strategic patent writing and portfolio development.