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"Derma Sciences: Drug Extends Wound Healing"
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PRINCETON, N.J. (TheStreet) —Derma Sciences (DSCI) said an experimental wound-healing drug demonstrated prolonged efficacy in patients with diabetic foot ulcers, according to new follow-up data released Wednesday from a mid-stage study. Executives with Derma Sciences say they will meet with the U.S. Food and Drug Administration this fall to discuss the results from the phase II study of the wound-healing drug DSC127 and set the design for pivotal phase III studies which could begin in the first quarter of next year.

After 24 weeks, 73% of patients with diabetic foot ulcers treated with daily topical applications of DSC127 had complete wound healing compared to 46% of patients treated with a placebo or standard of care. The 27% improvement in wound healing favoring DSC127 over placebo at 24 weeks was more pronounced than was reported about the drug's wound-healing effect at 12 weeks.

Last February, Derma Sciences reported that 54% of DSC127-treated patients had complete wound healing after 12 weeks compared to 33% of placebo patients—a margin of 21% favoring DSC127.

The benefit of DSC127 over placebo at both 12 and 24 weeks was not statistically significant, although the study was not designed to demonstrate statistical significance, Derma Sciences said.

The phase II study enrolled 80 patients with diabetic foot ulcers resistant to healing with best standard of care. The patients were randomized to one of two doses of DSC127 (applied daily as a topical gel) or a placebo gel and treated for four weeks followed by eight weeks of observation. Wednesday's results came from a follow-up analysis exploring the continued effects of the drug after another 12 weeks of observation.

DSC127 is designed to stimulate receptors in cells at the wound site that, in turn, recruit stem cells that promote new skin and blood vessel growth and accelerate wound healing.

Last week, Shire paid $750 million to acquire Advanced BioHealing, makers of an artificial skin used to heal diabetic foot ulcers. Derma Sciences' DSC127, if approved, would compete against Dermagraft, the wound-healing product acquired by Shire in the Advanced BioHealing deal.

DSC127 has the potential to be a more effective and easier to use wound-healing agent than Dermagraft, based on the phase II data, said Ed Quilty, Derma Sciences' CEO, in an interview Tuesday evening.

Derma Sciences closed Tuesday at $9.35.