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Development of DSC127 for the treatment of diabetic foot ulcers

Kathleen Rodgers
University of Southern California, USA

Abstract

Diabetes is a disorder that is well known to delay wound repair resulting in the formation of colonized, chronic wounds. The resultant ulcers contribute to increased risk of morbidity, including osteomyelitis and amputations, and increased burden to the health care system. The only active product approved for the treatment of diabetic ulcers, Regranex, is not widely used due to minimal proven efficacy and recent warnings added to the Instructions for Use regarding increase rate of mortality secondary to malignancy. NorLeu^3-angiotensin (1-7) (NorLeu^3-A(1-7)) is undergoing development as an active agent for the treatment of diabetic wounds. NorLeu^3-A(1-7) is an analogue of the naturally occurring peptide, angiotensin 1-7. The mechanisms of action include induction of progenitor proliferation and accelerated vascularization, collagen deposition and re-epithelialization. Research to date has shown that NorLeu^3-A(1-7) is highly effective in the closure of diabetic wounds and is superior to Regranex in animal studies. In a randomized, double-blind, placebo-controlled Phase 2 clinical trial of patients with chronic, non-infected, neuropathic or neuroischemic plantar Wagner Grade 1 or 2 foot ulcers, DSC127, a topical clinical formulation of NorLeu^3-A(1-7), was assessed for safety, complete wound closure and durability of effect. DSC127 showed a dose-dependent reduction in area from baseline and median time to complete healing, as well as an increase in complete wound closure at 12 weeks. Studies to date have shown that DSC127 is safe and effective in accelerating the healing of diabetic foot ulcers.

Biography

Kathleen Rodgers completed her Ph.D in 1984 and joined the faculty at the University of Southern California in 1986 after completing a postdoctoral fellowship. She has focused her career on drug discovery and preclinical development of therapies for the regeneration of damaged tissue. Currently she has developed several products with marketing approval and several others in clinical development including DSC127. She has published over 120 papers in the fields of toxicology, immunology, device development and exploitation of the renin angiotensin system as a platform for drug discovery.