

DFU-884 for the Treatment of Diabetic Foot Ulcer

Overview

Drug Name	DFU-884
Description	DFU-884, a DNA vector expressing two isoforms of hepatocyte growth factor (HGF), is in clinical development for the treatment of patients with chronic non-healing foot ulcers.
Target	Hepatocyte Growth Factor
Drug Modality	Plasmid DNA
Indication	Diabetic Foot Ulcer
Product Category	Gene Therapy
Mechanism of Action	Inducing Angiogenesis to Improve the Microcirculation
Status	Clinical Trial
Patent	Granted

Seeking Global Cooperation

Protheragen Inc. is actively seeking partnership for DFU-884. Potential collaboration can be strategic alliance, licensing, or marketing agreement.

We look forward to hearing from you.

Target

Hepatocyte Growth Factor (HGF)

This gene encodes a protein that binds to the hepatocyte growth factor receptor to regulate cell growth, cell motility and morphogenesis in numerous cell and tissue types. Alternative splicing results in multiple transcript variants, at least one of which encodes a preproprotein that is proteolytically processed to generate alpha and beta chains, which form the mature heterodimer. This protein is secreted by mesenchymal cells and acts as a

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multi-functional cytokine on cells of mainly epithelial origin. This protein also plays a role in angiogenesis, tumorigenesis, and tissue regeneration. Although the encoded protein is a member of the peptidase S1 family of serine proteases, it lacks peptidase activity. Mutations in this gene are associated with nonsyndromic hearing loss.

Indication

Diabetic Foot Ulcers

Foot ulcers and complications thereof are a leading cause of hospitalization and lower extremity amputation among patients with diabetes. 10-15% of diabetic individuals are at risk of developing ulcers. Infected diabetic foot ulcers were responsible for more than 80% of all amputations in the US from 2005 to 2010. In the US, diabetic foot ulcers generate costs in excess of USD 1 billion, including costs to Medicare and private insurers of approximately USD 9-13 million per year.

The initial lesion may result from acute trauma, injury or from chronic mechanical stress. The development of wounds and ulcers of the lower extremities in diabetic patients is complicated because of neuropathy. Distal ischemia secondary to peripheral vascular disease is another potential cause of ulceration, and is an important risk factor for amputation. Early identification and treatment of wounds are key to the avoidance of infection, as infectious complications can be life- or limb-threatening. When infection does develop, identification of the infecting microorganism is essential for selection of the appropriate antimicrobial agent, since improperly treated skin infections have the potential to spread to bone, resulting in osteomyelitis. Even in the absence of infection, severe foot wounds are extremely slow to heal due to deficiencies in the intrinsic wound-healing system of diabetic patients.

Mechanism of Action

Inducing Angiogenesis to Improve the Microcirculation

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Molecular Mechanism HGF may induce new blood vessel formation locally by activating various signaling pathways.

Status

The Status of DFU-884

The international patent applications under the PCT have been granted.

