

# Topical IL-1Ra (anakinra) in the form of gel to treat persistent diabetic skin and corneal wounds

Published date: May 25, 2016

## Technology description

### Background

Anakinra (aka. Kineret) is a recombinant human IL-1Ra that was developed by Amgen. It is currently used to treat moderately to severely active rheumatoid arthritis, but also treats neonatal-onset multisystem inflammatory disease (NOMID). Anakinra is given as an IV dose and the drug is no longer under patent. The properties of Anakinra are well known, and it is commercially available as a generic drug. Our inventors are working on reformulating the generic drug, from an IV injected liquid to a topical gel. The new Anakinra gel formulation could be used directly on wounds or pre-applied to wound care products such as wraps, bandages or medical devices.

Regranex is a FDA approved gel for diabetic ulcers from neuropathic incidence (~40% of diabetic ulcers). The new formulation could be combined with Regranex® (aka. Becaplemin) for neuropathic ulcers (40% of foot ulcers) to enhance its effects (re-epithelialization + granulation). An alternate use for the product may be in the treatment of severe burns, an injury that also requires re-epithelialization.

Diabetes affects approximately 170 million people worldwide, including 20.8 million in the US, and by 2030 these numbers are projected to double. The American Diabetes Association (ADA) released new research on March 6, 2013 estimating the total cost of diagnosed diabetes have risen to \$245 billion in 2012 from 174 billion in 2007, when the cost was last estimated. The total estimated cost of diagnosed diabetes in 2012 is \$245 billion, including \$176 billion in direct medical costs and \$69 billion in reduced productivity. One area where wound healing in diabetics is an acute problem is in nursing homes where diabetics are at higher risk of getting bed sores and pressure ulcers. In 2004, nearly 25% of all residents in nursing homes had diabetes as a primary admission and/or current diagnosis. Although specifics on pressure ulcers were not found specifically for diabetics, over 3 million patients were treated in US healthcare facilities each year at a cost of \$15.6 billion.

Currently Regranex is the only prescription gel that accelerates the healing of diabetic ulcer, and it is only approved for diabetic ulcers from neuropathic incidence. This new formulation may be a potent treatment for diabetic ulcers either on its own or in combination with Regranex. This provides a large market opportunity with little competition.

## Institution

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