PESKIN® PHARMACEUTICALS

The green drug company®

EZTREK® – LIPID-BASED ORAL MEDICAL FOOD FOR DERMAL WOUND HEALING

Problem: Wound Healing

Wound healing is the physiological response to tissue injury. The ability of any wound to heal is dependent on the extent of injury, time from wound occurrence to care, individual immune, and inflammatory responses, and microbial colonization. Control of inflammation in chronic non-healing wounds is critical as healing proceeds only after inflammation is controlled. Dysfunction and dysregulation of inflammation, as well as immune response in wound healing, causes increased morbidity and mortality. Chronic wounds, such as diabetic foot ulcers, negatively impact patient quality of life and productivity. $50B per year is spent on wound care. Chronic diabetic foot ulcers (DFUs) alone represent a substantial financial burden to the health care system costing up to $13B per year.

Current medical treatment for chronic wounds includes surgical debridement, negative pressure wound therapy, and exogenous cytokines and growth factors. The only growth factor to have shown clinical efficacy is a recombinant PDGF gel (Regranex®); however, many chronic wounds do not respond. Moist wound care, bioengineered skin, negative-pressure wound therapy (NPWT), aspirin, ultrasound therapy, and hyperbaric oxygen therapy (HBOT) are of limited treatment benefit. Clearly, novel therapies to control inflammation and enable the natural wound healing process are desperately needed so that both military and civilian patients can experience a better quality of life.

Warfighter and Veteran Relevance

Improvements in body armor have improved survivability of combat wounds; however, survivors typically suffer devastating wounds to the extremities. Inefficient wound healing can result in the development of chronic wounds, with or without amputation. Military combat environments pose unique and difficult challenges for the treatment of injured warfighters. Access and time to treatment are quiet often delayed – increasing exposure to numerous pathogens on the battlefield, and at subsequent point-of-care hospitals and clinics.

There is a significant, unmet medical need for an effective, cost-effective, and non-toxic treatment to improve healing of a broad spectrum of chronic dermal wounds. A high percentage of dermal wounds fail to heal with conventional therapy, resulting in impaired lifestyle, disability, and potential amputation. One common type of dermal wound in a hospital setting is a pressure ulcer caused by unrelieved pressure, damaging skin and underlying tissue. They are easily infected, requiring more invasive and costly medical interventions. Both hospital costs and lengths of stay are significantly higher for military patients who develop pressure ulcers during hospitalization – more than $50,000 per patient and $1.5B annually.[1]

Pressure ulcers pose cause for concern in acute care Department of Defense and Veterans Administration hospitals. In acute care patients, the pressure ulcer incidence (new cases appearing during a specified time period) and prevalence (a count of the number of all cases, both old and new, at a specific point in time) have been found to be as high as 30%. Some subpopulations may be at higher risk – such as warfighters and veterans with spinal cord injuries (39% prevalence).[1]

Solution: EZTREK®

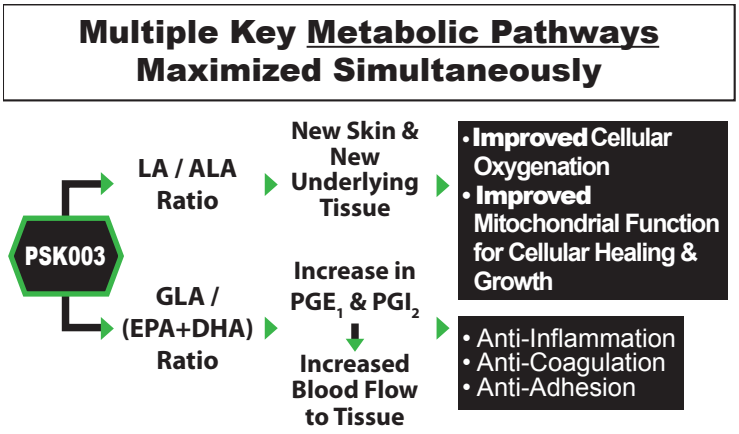
EZTREK®, a novel ingestible Medical Food, which could represent the first effective ingestible medication to expedite wound healing. The active ingredients of EZTREK® are botanical lipids, i.e., plant-based lipids:

- Linoleic acid (LA)
- Alpha-linolenic acid (ALA)
- Gamma-linolenic acid (GLA)
- Docosahexaenoic acid (DHA)

For projected maximum clinical strength and patient tolerability, EZTREK® utilize san unprocessed, natural triglyceride form, with an inherent range of the naturally occurring active ingredients. EZTREK® is a lipids-based plant seed oil composition

[1] As referenced in VA Inspector General Report, Management in Patients with Pressure Ulcers in Veterans Health Administration Facilities, March 22, 2006.

with a unique and novel approach in combatting diabetic ulcers—by employing multiple metabolic pathways simultaneously (figure right). One pathway involves the ratio of two essential fatty acids, LA (parent omega-6) and ALA (parent omega-3). The second involves the ratio of GLA; an omega-6 fatty acid metabolite (FA), to a combination of Eicosapentaenoic acid (EPA; an omega-3 FA metabolite) and Docosahexaenoic acid (DHA; an omega-3 FA metabolite). Peskin has three patents that together protect the intellectual property behind its development. Both chemically synthesized and nonsynthesized compositions of EZTREK® are covered by patent.



Preclinical Data

The Medical Food, EZTREK® taken orally: a) causes rapid sealing of the wound via key substrates in its composition, b) reduces inflammation via enhanced PGE1 production, c) increases cellular oxygen (decreases hypoxia) via increased mitochondrial efficiency, d) increases blood flow/arterial support via prostaglandin maximization of both PGE1 and PGI2 which also increase nitric oxide (NO) levels, and e) maximizes mitochondrial efficiency so that cellular energy is increased—allowing expedited healing of underlying tissue.

The composition directly allows increased insulin binding sensitivity so neuropathy is decreased. This effect reduces elevated blood glucose levels. Anecdotal clinical evidence in three patients given the EZTREK® precursor achieved improved blood flow and wound healing.

Product Development Plan

The FDA has published a list of substances that are "generally recognized as safe" (GRAS). The components in EZTREK® are plant-based edible oils (from seeds). These particular oils have a GRAS designation by the FDA. Therefore, we believe significantly fewer toxicity/pharmacologic studies will be required than for a completely synthesized drug. We also believe that fewer potential side effects will result and patient compliance will be greater. The FDA has allocations for botanical-based drugs. The FDA's section 505(b)(2) may be utilized to shorten the clinical development pathway. We plan regular discussions with the Agency to clarify the regulatory path to product approval.

About Peskin Pharma (Houston, TX): We specialize in product development using lipids-based pharmacognosy, derived from natural plant-derived sources—specifically, seed oils. Digitalis, Codeine, Ephedrine, and Taxol® are examples of plant-based drugs. Our approach focuses on state-of-the-art novel strategies in research and development of plant-based lipids. Peskin Pharmaceuticals was created to advance and commercialize discoveries from decades of medical research in wound healing, and diabetes-related diseases – with natural extensions into the cardiovascular, inflammation, and cancer sectors.