REGENICIN

advancing the field of regenerative medicine

About Regenicin

Regenicin, Inc., (OTC Bulletin Board: RGIN.OB) is a biotechnology company specializing in the development and commercialization of regenerative cell therapies to restore the health of damaged tissues and organs. Regenicin, which was founded in 2010, has assembled a world class team with a proven track record for developing and bringing innovative medical devices and biotechnology products to market. Regenicin is playing a critical role in the development of the therapeutic candidate, PermaDerm™, an exciting breakthrough technology that uses the patient's own skin cells to generate living, tissue-engineered skin for the treatment of chronic burns. The company is publicly traded with headquarters in New Jersey.

PermaDerm™ Overview

PermaDerm™ is being developed to be the only tissue-engineered skin prepared from autologous (patient's own) skin cells consisting of both epidermal and dermal layers. A small harvested section of the patient's own skin can be grown to graft an area one hundred times its size in as little as thirty days. These living self-to-self skin graft tissue are intended to form permanent skin tissue that will not be rejected by the immune system of the patient, a critical possibility in porcine or cadaver skin grafts used today.

PermaDerm™ has been clinically tested in over 150 pediatric, catastrophic burn patients. Currently Regenicin is working with its contract manufacturer to obtain Pre-Market Approval from the FDA for PermaDerm™.

An insurance company procedural code has been approved for reimbursement of costs to hospitals. The American Medical Association has assigned CPT (Current Procedural Terminology) code for cultured skin substitutes under the dermal substitute category which enables insurance companies to process and hospitals to be reimbursed for cultured skin substitutes once approved by the FDA.

The Science

The investigational product PermaDerm™, is composed of cultured fibroblast and kerotinocytes on a collagen substrate (biomedical polymer) that produces a living skin substitute that contains both epidermal and dermal components.

The Process

A small full thickness section of skin is harvested from the patient. Skin cells (kerotinocytes and fibroblasts) are then isolated from the harvested section in the cell therapy facility and cultured separately in nutrient media in order to expand

the cell populations. Cell expansion in the cell therapy facility allows for the production of a large number of grafts from a small harvested section from the patient. The cells are then combined with the proprietary biopolymer substrate which is fabricated from collagen. Cells organize themselves on the biopolymer to ultimately mimic the structure of normal skin. The final skin product will be shipped to the clinical site and surgically grafted onto the burned areas of the patient.

Potential Benefits

PermaDerm™ is being developed to produce the following benefits:

Alternative to Harvesting Skin from Multiple Uninjured Sites

Victims of large burns do not possess sufficient skin to cover the burn wound without re-harvesting skin from multiple uninjured sites at 7-10 day intervals. PermaDerm will be grown in sufficient quantities to treat burn victims with severe burns over 50% of their body.

Grown from Patients' Own Skin Cells

A small harvested section of the patient's own skin can be grown in the Cell therapy Facility into a sufficient number of pieces of PermaDerm™ one hundred times its area in as little as thirty days. These self-to-self skin grafts are intended to form permanent skin tissue that will not be rejected by the immune system of the patient, a critical possibility in porcine or cadaver skin grafts used today. PermaDerm™ will avoid the necessity of a lifetime regime of immunosuppressant drugs, which are costly and also may have serious side effects.

Decrease Life Threatening Infection

Sepsis, which develops from infections, accounts for 75% of deaths from burn injuries, and is often associated with multiple organ failure. PermaDerm™ is being developed to eliminate the need to remove large amounts of the patient's own skin for grafting and reduce the chance of a life threatening infection.

Lowers Risk of Rejection

PermaDerm™ is being developed to lower the risk of rejection by the immune system because it's grown from the patient's own skin cells, unlike porcine or cadaver skin, which pose a critical possibility for rejection.

Stretches & Grows with Patient

PermaDerm™ is expected to stretch and grow with patients because it contains both the epidermal and dermal layers. The dermal layer has viable, living cells that can attach to the body and continue growing. This feature also potentially eliminates the need for future grafting.

Reduces Health Care Costs

It is anticipated that PermaDerm will reduce healthcare costs by decreasing the patient's stay in the Critical Care Unit, a cost that can reach upwards of $7,000 per day.

Additional Applications

By scientific rationale, PermaDerm may be developed for patients with chronic wounds.

Addressing a Critical Need

- According to the American Burn Association, there are currently over 2,000 cases annually involving burns covering over 50% of the patient's total body surface.[1]
- Expenditures for treatment of burns in the U.S. is estimated at $3 billion annually.
- Burns in the civilian population cause more than 900,000 hospital days in the US annually.[2]
- Sepsis, which develops from infections, accounts for 75% of deaths from burn injuries, and is often associated with multiple organ failure.
- Mortality and morbidity from burns, trauma, and other skin loss injuries remain significant medical and socio-economic problems estimated to cost more than $1 billion annually in treatment costs and lost productivity.

[1] American Burn Associations 2009 Fact Sheet
[2] (Hall, JR The total cost of fire in the United States through 1991. In Quincy MA ed. National Fire Protection Association.1993:1-20).