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Lenipsor⁺ innovative care for psoriasis disease

THE INNOVATION

iDelivery developed an innovative (patented) and efficient care for psoriasis disease. A topical low cost treatment to cure the psoriatic plaque with re-bound, average time of ten months. The treatment is derived by a plant phyto complex extract. At the moment, Idelivery has isolated the active molecules from the complex compound and is carrying out the validation studies.

PRELIMINAR RESULT

The in vitro tests were carried out on an experimental model of psoriasis stimulating a cell line of human keratinocytes with interleukin 6 (one of the pro-inflammatory factors present in psoriasis) and then treating with various concentrations of the freezedried decoction. The experimental results obtained have shown that the effect on growth inhibition produced by the solution of the decoction is both time and dose dependent, already after 48 h of treatment with the decoction to 0.1%, there is a reduction of the inhibition of growth equal to about 50% (the cell hyper proliferation is characteristic of psoriasis).

The in vivo tests were performed on 50 volunteers suffering from psoriasis in different stages of the disease. All subjects were treated by applying the treatment directly on the psoriasis plaques, twice a day. The various parts of the body affected by psoriasis were rubbed for about 20 min with the compound. Subjects were evaluated at intervals of one week until remission of skin manifestations related to psoriasis. All subjects showed an improvement after just one week, and 100 % of subjects after one month showed complete remission of the disease rashes . The subjects were followed in the course of post - remission and 100% of the subjects showed an average lag-time before the reappearance of cutaneous manifestations of about 10 months. The subjects (38 %) in which have recurred symptoms of the disease, were treated with the same modalities of the first treatment and remission occurred for all subjects within 2 weeks.



The Benefits

The proposed treatment has several advantages:

- Increased efficacy of care;
- Low cost treatment:
- Short time regression of psoriatic plaque (one week);
- Last longing results for cycle of care (10 months);
- Absence of contraindication or side effect;

THE PROBLEM

Psoriasis is a serious inflammatory, non communicable autoimmune disease, which carries severe physical, psychological and socioeconomic burdens on over 125 million people worldwide. It is estimated that at least 10 percent of psoriasis sufferers have a severe form that causes disability and exclusion from a normal life. Economically, in the U.S. alone, impact is estimated that Americans with psoriasis lose approximately 56 million hours of work and spend \$2 to \$3 billion to treat the disease every year. Developing countries with less resources and healthcare have an even greater economic burden due to the lack of access to reliable diagnosis or risk for misdiagnosis of the disease, stigmatization and discrimination, and little-to-no access to affective treatments. Although there are numerous treatments for psoriasis, many still face a very poor quality of life because the treatments do not work, work poorly, are too expensive, or are not available to them. According to the National Psoriasis Foundation, in 2010 there were 34 drugs in the psoriasistreatment pipeline in various clinical stages of the approval process.

(1) Many of the new drugs are Biologics and inhibit the immune system from over-reacting or over-producing certain cells. Each Biologic product costs on average about \$800 million U.S. dollars for pharmaceutical companies to produce, from conception-to-the-shelf, and once released to the public, cost on average around \$11,000 to \$18,000 a year, depending on the dose and the drug(2).

The extremely high cost of biologic medications for the national social security / health systems or the patients is one of the reasons why psoriasis is undertreated, yet many of the new treatments are biologic. Despite the dearth of medications available to treat psoriasis, a study by the National Psoriasis Foundation and Amgen reported that "nearly 40% of the 1,142 patients surveyed with chronic moderate or severe psoriasis are not currently receiving any treatment," and more than half of the patients are not be treated as recommended by American Academy of Dermatology guidelines.(3) 73% were only using topical treatments.

Factors for lack or low treatment are health insurance issues, fear of the biologics (because the immune system is comprised), increased risk of side effects from the systemic and biologics, very high cost, low efficacy of the systemic, and lack of access to health care. The European Federation of Psoriasis Patient Associations (EUROPSO) undertook a Europe-wide survey(4) to examine the quality of life and patients' perspectives on treatment and their disease and found that of the 17,990 respondents that had psoriasis. The greatest impact was on activities of daily living, especially affecting clothing choice, bathing routine and sporting activities. Overall, 77% replied that psoriasis was a problem or a significant problem. While patients were satisfied with the information and care from their dermatologist (40% highly satisfied), available treatment options were less satisfactory, with over 70% reporting only low to moderate satisfaction.

- 1) "Research Pipeline." National Psoriasis Foundation. http://www.psoriasis.org/netcommunity/treating_psoriasis, Jan. 2011.
- 2) Morrow, Thomas, M.D. "Cost-E□ective Psoriasis Treatment May Demand Creative Coverage Rules:, Managed Care, May 2006. http://www.natbiocorp.com/pdfs/managed-care-May06.pdf
- 3) National Psoriasis Foundation. "Survey indicates people with chronic moderate to severe plaque psoriasis may be under-treated." http://www.psoriasis.org/news/press/2007/20070202_survey.php.
- 4) L. Dubertret, L.; U. Mrowietz; A. Ranki; P.C.M. van de Kerkhof; S. Chimenti; T. Lotti;
- G. Schäfer "European Patient Perspectives on the Impact of Psoriasis: the EUROPSO

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