MEDCARA PHARMACEUTICALS

wartpeel® (Patented Compounded 5Fu, sal acid)

Drug Discovery, Dermatological

Topical Treatment for Non-Genital Resistant Warts

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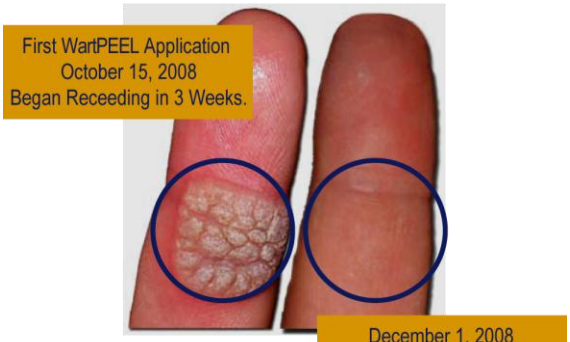

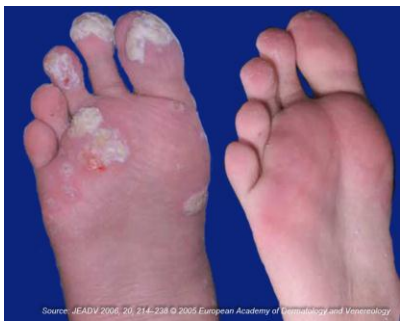

HIGHLIGHTS

RECENT

- Patent issued Q1-2010. **U.S. Patent No. 7,655,668** directed to a "Composition and Method for Treatment of Warts." The claims of this patent are all directed to a wart treatment composition that includes 5-fluorouracil (5-FU) and salicylic acid.
- Pre-IND meeting with FDA completed. MedCara has been cleared to begin Phase I/II for Wart indication
- Over 60,000 patients successfully treated over the last 12 years.
- 2011 compounding revenue was $950K with 12,252 prescriptions from over 1,700 prescribers
- Published study from Mayo Clinic
- Cure rate of 88% + for resistant warts.

UPCOMING

- Proof of Concept Study scheduled for Q2-12 with Wake Forest University Dermatology
- Formulation and stability review scheduled for Q4-12 with University of Iowa Pharmaceuticals pending grant approval.
- Grants totaling $248K have been secured to fund pre-IND filing research.
- Once NDA issues, WartPEEL will be the first FDA approved topical treatment for resistant warts

KEY LEADER SUPPORT

"We observed a high rate of therapeutic success treating predominantly recalcitrant warts with a topical liquid formulation (WartPEEL) containing chemotherapeutic agents. Use of a liquid preparation is more appealing than the destructive approaches frequently used (liquid nitrogen, electrodessication, curettage, excision, CO2 laser), all of which cause some degree of morbidity. Our patients reported infrequent adverse effects using this compound. We conclude that this topical formulation, which incorporates chemotherapeutic agents, is an effective treatment for warts. Although a survey study has limitations, we believe our results warrant further study."

Mark Davis, MD Department of Dermatology, Mayo Clinic, Rochester, MN

Innovation, Significance and Impact Statement

In the U.S. approximately 10% of the population will be will be afflicted with non-genital warts[1]. They can greatly affect a patient's quality of life by causing pain, embarrassment, fear of negative appraisal by others and frustration caused by persistence and/or recurrence. In 51.7% percent of patients moderate to extreme discomfort is reported, and 38.8% have their ability to enjoy social or leisure activities affected to a moderate to extreme degree.[2] Many wart cases regress spontaneously within 2 years[3], however, previously infected patients have a higher risk for development of new warts than those never infected[4] and many of these patients may require follow-on care If a wart persists, after an over the counter (OTC) treatment course, there are a variety of alternative clinic based treatment modalities and approximate costs such as; liquid nitrogen ($1,248), pulse dye laser ($690), Aldara ($1,500), Candida ($381), CO2 laser excision ($356), and bleomycin ($669) that can be utilized as a second line treatment.

While these treatments may or may not successfully treat the wart(s) they can be painful and according to an article in the Journal of Drugs In Dermatology the average cost of treatment is $807 (taking into consideration the physician.procedure and drug costs) . Often after exhausting all other treatment options many patients suffer with recurrence , and the lack of alternatives forces them to live with their resistant wart. The lack of an approved, prescription product for the eradication of warts has led to significant fragmentation and patient frustration with the treatment options. New products for wart treatment have grown the total market for wart treatments with insignificant erosion of the established products. Patients are clearly dissatisfied with the painful treatment options often requiring repeated visits to specialists which also increase the total costs to payers and increase employee absenteeism. The wart treatment market clearly represents a significant opportunity with payers and patients both aspiring for improved treatment options.

It is due to this unmet patient need, the lack of success with OTC treatments and the pain, discomfort, and cost of the available second line treatment modalities that MedCara has developed a novel, low cost, non-invasive, topical treatment for recalcitrant warts in adults. Through MedCara's affiliation with its sister company Nucara, a rural market pharmacy and drug compounders, over 2000 physicians have used MedCara's compounded formulation (Med 101). These podiatrists, dermatologists, family practice and other health care professionals have treated approximately 60,000 patients with very positive results. The positive feedback from prescribing physicians and satisfied patients combined with results from small clinical studies performed by the Mayo Clinic and other clinical researchers convinced MedCara that they could help more patients, and alleviate the physical and monetary costs associated with wart removal by commercializing Med 101.

MedCara's treatment for recalcitrant warts addresses the proliferative nature of wart growth. The combination of salicylic acid (SA) and 5-fluorouracil (5-FU) helps to prevent wart regrowth and recurrence by means of (SA's) exfoliating properties and (5-FU's), noted antimitotic and anti-proliferative qualities. These two therapeutic characteristics work synergistically to eradicate the wart and discourage regrowth or recurrence with little patient discomfort. Current treatment standards fail to deal with the proliferative nature of warts and thus, may eliminate the superficial wart but do not address the underlying cellular growth, which is responsible for wart recurrence. In addition, all of the clinic-based treatments are relatively more expensive than Med 101, can be very painful, and do not ensure a successful outcome for the patient. MedCara's goal is to seek FDA approval for Med 101 and thereby expand the availability of Med 101 to the more than 4 million people who have warts that are resistant to first line treatment (OTC salicylic acid).

Only approximately 40% of the 4 million patients with resistant warts currently seek further treatment, however with the introduction of an FDA approved topical treatment option for adults, it is estimated that this will increase to just over 50% of resistant wart patients, or a patient population of over 2 million in 2018.

If MedCara is successful with their goal they will be able to lower patient morbidity and reduce the monetary cost of treating recalcitrant warts to patients and payors by approximately 90%.

The purpose of this application is to perform a detailed assay method validation and stability testing according to ICH guidelines for Med 101. MedCara has chosen to work with a team from The University of Iowa Pharmaceuticals, the only FDA approved cGMP manufacturer affiliated with a research university, to perform these tests and will use information and results of this research to formalize Med 101's product presentation, and patient use standards.

WartPEEL (MED-101)

MedCara plans to enter MED-101 into clinical development and market the approved product as WartPEEL—the first FDA approved topical prescription drug available for the treatment of resistant warts.

Formulation – MED-101 is a mixture of 5-fluorouracil (2%) and salicylic acid (17%) in a proprietary base. The FDA has previously independently approved both active ingredients for human use.

Discovery – MED-101 was discovered in the experimental pharmacology department of NuCara pharmacies and the formulation refined through the coordination of participating physicians.

Previous Human Experience –WartPEEL has already been used in humans and over 1,700+ physicians annually prescribe the product in their practice giving MedCara significant clinical, scientific, and market insight into the product. The product has a total cure rate of 88% compared to the average salicylic acid response rate of 60%.

Intellectual Property – **U.S. Patent No. 7,655,668** directed to a "Composition and Method for Treatment of Warts." The claims of this patent are all directed to a wart treatment composition that includes 5-fluorouracil (5-FU) and salicylic acid. Additional I.P. has been submitted for review scheduled in June 2012.

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