

HEALTH

Psoriasis sufferers to get relief - without steroids - from Israeli ointment

By Nicky Blackburn October 28, 2007

An Israeli start-up company is developing a new vitamin-based ointment for people suffering from psoriasis that promises to help relieve the debilitating symptoms of the incurable skin disease without the need for steroids.

DermiPsor, which was founded in January 2004, has already successfully passed Phase II clinical trials and is now waiting for FDA approval for Phase III trials. If all goes as expected, the new ointment, based on Vitamin B and D, could be on the market with FDA and CE approval by the end of 2009.

Psoriasis affects as many as 7.5 million Americans according to the National Institute of Health, and two to three percent of the world's population. It is not life threatening, but it does have a huge impact on the quality of life of patients, who often suffer ugly red patches or lesions (plaque psoriasis) covered by a build up of dead skin cells all over the skin.

"It can be very horrible and embarrassing for the patients, covering half their bodies. It's itchy and painful, and they often can't sleep well at night," says Zeev Even-Chen, the CEO of DermiPsor. "It's a disease that hurts the person's quality of life."

While severe cases are treated with expensive systemic drugs, for mild to moderate psoriasis sufferers (85% of those with the disease) the treatment path as a first line of defense is mainly topical. Researchers believe psoriasis occurs when inflammation and faulty signals in the immune system cause skin cells to grow too rapidly without maturation. Topical creams and ointments slow down or normalize this excessive cell proliferation, and can reduce inflammation and redness.

The most frequent ointment treatments used for psoriasis are based on vitamin D derivatives, and steroids, but they have some major drawbacks. According to Even-Chen, patients who use steroid creams and ointments often suffer from skin atrophy and a rebound effect (once they complete treatment, their psoriatic symptoms reappear in a worse form than before they started using the steroid cream). Another drawback is the

need to increase the steroid dosage over time to get optimal effectiveness.

"Since psoriasis is an incurable skin disease, all treatments offer only temporary relief," Even-Chen told ISRAEL21c. "Steroids have many long-term side effects and you go into relapse whenever you stop the drugs."

DermiPsor hopes to change all this. The company's ointment is based on vitamin D and B, and it contains no steroids. In Phase I/IIa double blind clinical trials on 120 patients tested for safety and efficacy, which ended in July 2006, the patients were divided into three test groups, one group received a placebo, another received DermiPsor's ointment and the third the Dovonex ointment, a US ointment based on a vitamin D derivative, which is considered the gold standard topical treatment for psoriasis.

Despite the fact that the active ingredient in DermiPsor's ointment was not optimized, it performed well in comparison to Dovonex.

"It was found that our ointment was very safe without significant adverse events, non inferior efficacy to the "gold standard" Dovonex and no rebound effect," says Even-Chen.

Phase II clinical trials followed in February 2007, and took place at five FDA-approved centers in Eastern Europe. This time, 168 patients took part in the double-blind study, but they were treated bilaterally (each side of their body receives a different treatment), doubling the number of treatments and results. The patients were divided into seven groups.

"The results indicate that DermiPsor's ointment is superior to the gold standard," says Even-Chen. "The trial results were analyzed based on stringent criteria that the FDA requests in Phase III trials - recording the frequency of patients in each treatment group who achieved clear to almost clear psoriasis at the end of the treatment period. This is much harder than if you take an average improvement of symptoms in a group in which some people respond better, some less, but we choose the 'clear, or almost clear' stringent criteria."

The trial also helped the company identify the optimal combination of active ingredients to give the highest efficacy.

DermiPsor now plans to submit a request for final Phase III trials with the FDA. The trial will take place in a number of medical centers in the US, Canada, Europe and Israel and will involve about 1,000 patients treated for 12 weeks.

Even-Chen estimates that the trials will begin in the second or third quarter of next year, and will be completed within 10-12 months, depending on recruitment.

DermiPsor was founded at the Meytag Technology Incubator in Katzrim in the Golan Heights by dermatologist and pediatrician Dr. Avikam Harel and his assistant, Dr. Oglia Bloch. Today it employs just two people - Even-Chen and an administrative aide, and the rest of the work is outsourced to keep costs low.

Early in its life, the company recruited two leading experts in the world of psoriasis to its scientific advisory board: Prof. Alice Gotlieb, from Tufts, New England Medical Center in Boston, and Prof. Mark Lebwohl, from the Mount Sinai School of Medicine in New York, to its scientific advisory board. "This has given great value to the company," says Even-Chen.

The company raised about \$1.8 million in two rounds, held in 2005 and January 2007. Investors include Capital Point, and private investors - Noam Lanir (founder of Empire Online), Benny Alagem (founder Packard Bell), and Shayt Almogim.

DermiPsor plans to leave the incubator at the end of October and is now looking for additional funding from a strategic partner to help it through the final clinical trials. It is also looking for staff to fill several managerial positions. "The whole business has started to be large enough that one man can't cover it," says Even-Chen.

As for the future, one thing is sure, he adds. "This is not a one-product company. We have plans in several directions to make additional products in the dermatology, cosmetics, and cancer fields."

In the meantime, however, he plans to continue to keep a low profile. "Our philosophy is to work fast and to be very modest. I'm not looking for PR, but to create a new remedy that will help people suffering from psoriasis. Marketing will come at a later stage. There is no sense making large waves until we successfully accomplish Phase III trials."



-

-

-

