

Discovery at FAU may treat pre-cancerous skin lesions

By Glenn Singer
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Florida Atlantic University officials in Boca Raton have licensed rights to a therapy intended to treat a pre-cancerous skin condition commonly found in Florida. Two medical industry entrepreneurs now hope to further develop and market the discovery.

The potential product, a topical gel consisting of an existing cancer drug whose patent has expired and another chemical compound that adds a modified form of oxygen, could provide a simple way to treat actinic keratosis -- lesions that appear on the face and other parts of the body most often exposed to the sun.

The FAU-developed therapy would require clinical trials, and is at least several years away from the market. But if development goes well, the university could receive payments along the way and, eventually, royalties from sales.

There are a number of AK treatments, but they can produce discomfort and minor scarring. The FAU discovery -- the first potential drug licensed from the university's Center of Excellence in Biomedical and Marine Biotechnology -- does not appear to damage healthy cells.

Those involved in the project declined to name the chemicals being used in order to safeguard the patent application pending in Washington. The scientist who made the discovery, though, described the find as serendipitous.

"We actually stumbled onto the fact that adding the oxidizing agent produced better results than using the drug alone," said Professor Herbert Weissbach, director of FAU's Center for Molecular Biology and Biotechnology. "It's very exciting, but we could be even more excited about the prospects in a few months."

That's because dermatologists at the University of Alabama, after receiving permission from that school's institutional review board June 13, plan to test the gel on a small number of patients to see if it works. Results are expected in about six months.

AK, as it is called, is characterized by small crusty, scaly or crumbly bumps that arise on the skin surface and could affect a majority of those who reach age 80. Between 2 and 5 percent of untreated lesions may progress to squamous cell carcinoma, according to the Skin Cancer Foundation.

If the University of Alabama's "proof-of-concept" study shows the gel is effective, the next major step would be filing a new drug application with the Food and Drug Administration, said Stephen Chakoff of Miami, president of CHS Resources LLC. Chakoff has sold and designed assorted medical devices for about 30 years, and he formed CHS to work on the experimental compound.

He became the project quarterback after Weissbach, who performs research at Center of Excellence, brought his discovery last year to Jeannie McGuire, head of the university's technology transfer office. McGuire then arranged a meeting with Elliot Hahn, former president of generic drug maker Andrx Corp. and an investor in a number of medical ventures. Hahn suggested that Chakoff lead the effort.

Chakoff said he hopes early stage development will be funded by grant money. He received seed money from Enterprise Florida, the state's economic development agency, to apply for a \$100,000 grant from the National Institutes of Health. Additional NIH funding is possible, he said.

But that's just the start.

If the compound advances, Chakoff estimates bringing it to market could take several years of clinical trials and review and cost perhaps \$15 million. Hopefully, he said, he could raise that from individual investors.

While those involved would not discuss the financial arrangements in licensing the technology from FAU, such a deal typically involves payments to the university as a company reaches certain development milestones. Should a potential product make it to market, FAU probably would receive royalties from sales, as well.

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