FDA approves new skin cancer drug

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A new skin cancer drug tested for the first time in the world five years ago at the Virginia G. Piper Cancer Center at Scottsdale Healthcare just received expedited approval by the U.S. Food and Drug Administration, a remarkable accomplishment in new drug development.

Vismodegib (GDC-0449) was administered for the first time in the world Jan. 23, 2007, in a phase I clinical trial at Virginia G. Piper Cancer Center Clinical Trials at Scottsdale Healthcare, a partnership with the Translational Genomics Research Institute (TGen). Vismodegib received FDA approval on Jan. 30, 2012. Clinical trials progress through three phases and can take up to 10 years or more to successfully complete.

The drug is the first to receive FDA approval to treat inoperable basal cell carcinoma. Successful early trial results led to a broader subsequent study sponsored by Genentech. Continued positive study results led to Monday's FDA approval for marketing the drug under the name Erivedge.

Vismodegib is used to treat adult patients with advanced basal cell carcinoma, the most common type of skin cancer. It is intended for use in patients with locally advanced basal cell cancer who are not candidates for surgery or radiation and for patients whose cancer has spread to other parts of the body (metastatic), according to the FDA.

Arizona has one of the highest incidences of skin cancer in the world, and in the United States two million new cases of basal cell carcinoma are diagnosed every year. Most instances of basal cell cancer can be

effectively treated, but in some cases, the cancer cells spread and develop an aggressive form of the cancer that does not respond to standard surgical treatment.

"Until now, we did not have any treatments that can effectively slow the tumor growth in these patients with advanced skin cancer," said Daniel Von Hoff, MD, lead investigator. Dr. Von Hoff is physician-in-chief at TGen and chief scientific officer at the Virginia G. Piper Cancer Center Clinical Trials at Scottsdale Healthcare, where cancer patients receive treatment with promising new drugs.

"The drug works by inhibiting the Hedgehog pathway that is active in most basal cell cancers, preventing development, growth and survival of certain cancer cells. Results showed a durable clinical benefit – tumor shrinkage visible on X-ray or other physical exam or improvement in symptoms without tumor growth," said Glen Weiss, MD, director of Thoracic Oncology at Virginia G. Piper Cancer Center Clinical Trials and Clinical Associate Professor and Translational Physician Scientist at TGen.

Patient response during the clinical trials was assessed through physical examination and imaging. "Integrating genomic data with state-of-the-art clinical and imaging information to develop and apply targeted therapies has certainly taken a major step forward with the encouraging results from the Hedgehog trial," added Ron Korn, MD, a radiologist and medical director of the Virginia G. Piper Cancer Center at Scottsdale Healthcare.

San Francisco-based Genentech developed Vismodegib. Successful results of early clinical trials at the Virginia G. Piper Cancer Center at Scottsdale Healthcare, Johns Hopkins University and Karmanos Cancer Institute were published in the Sept. 17, 2009 New *England Journal of Medicine* and led to interest in increased access to the drug.

"In some patients there is progression to life-threatening, locally advanced or metastatic tumors. Approved as a pill to be taken once a day, we believe this new drug represents an opportunity to improve quality of life for these patients," said Dr. Weiss.

Provided by The Translational Genomics Research Institute

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