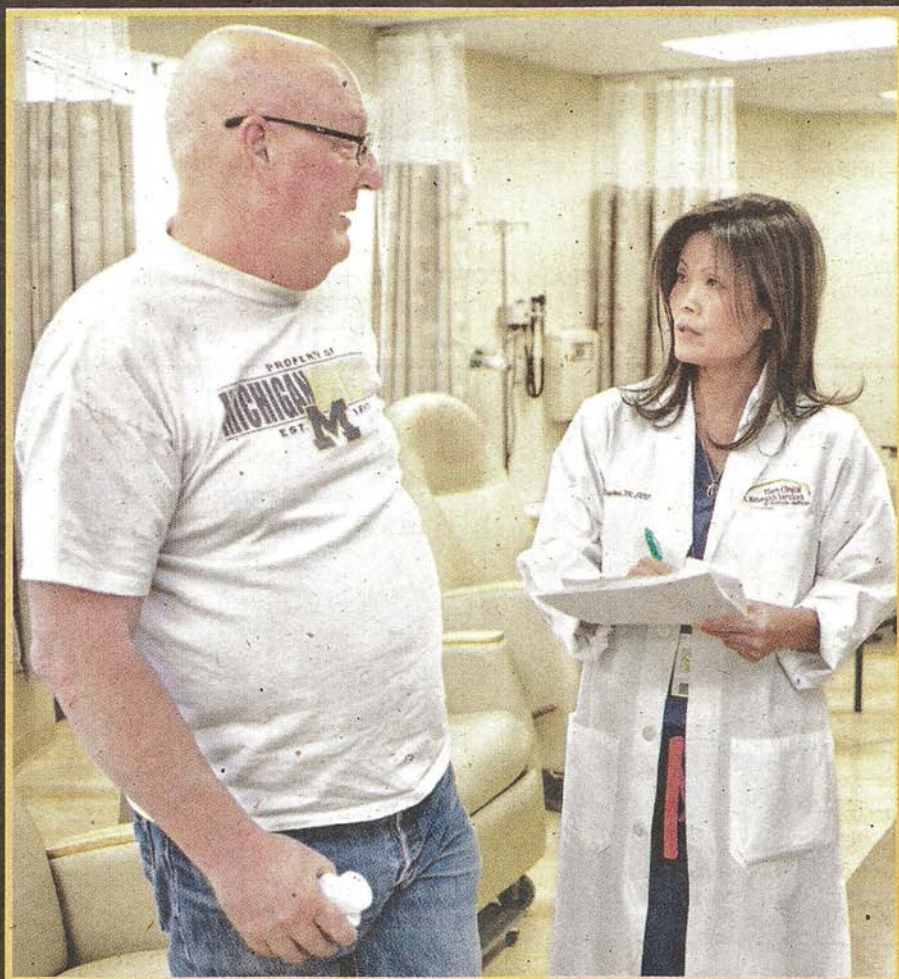


DRUG A 'MIRACLE'



For one patient, a drug being tested at Scottsdale Healthcare to treat a type of skin cancer is working wonders and it's on track to receiving FDA approval this fall.

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Jon Rykert talks with research nurse Lisa Blaydorn during his monthly checkup at the Virginia G. Piper Cancer Center. PHOTOS BY MARK HENLE/THE REPUBLIC

Cancer drug being tested in Scottsdale

By Sonja Haller

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Jon Rykert has flown into Phoenix 47 times in three years, once aboard the Southwest plane that in April had its roof rip open 30,000 feet in the air.

Rykert, 52, called that flight harrowing and crazy. But the Sacramento construction estimator will continue to fly to Arizona as long as doctors at Scottsdale Healthcare tell him he must, because what he finds here is some measure of peace — a “miracle drug.”

The drug, called GDC-0449, is expected to receive Federal Drug Administration approval this fall. The drug began testing in 2008 at the Virginia G. Piper Cancer Center Clinical Trials in Scottsdale, a partnership between the Translational Genomics Research Institute and Scottsdale Healthcare.

It would be the first drug connected to either institution to receive FDA approval.

Dr. Daniel Von Hoff, TGen's physician in chief, said the measured tones of doctors may disguise the milestone, but the drug's success has had a profound impact on those involved in studying it.

“It's the reason everyone exists and works to help somebody,” said Von Hoff, who also serves as chief scientific officer at Scottsdale Healthcare and US Oncology. “Everybody involved with this is very proud. And if it's done once, you can do it again.”

Von Hoff said the patients who first entered the trials with advanced basal cell carcinoma were in pain, disfigured and battling the disease in sometimes several organs. He said that after a few weeks with treatment, the shrinkage of tumors was dramatic.

Rykert was diagnosed with advanced basal cell carcinoma about 20 years ago. Basal cell skin cancer is common and easily treated — except in the rare case that it advances, when it can be deadly.

Rykert underwent at least 20 eight-to-10 hour surgeries to remove the cancerous tumors. When the tumors kept appearing, that was the only option he had. Other than cutting the tumors out, there is no standard of treatment for this form of advanced cancer. Finally, Rykert's doctor told him that he couldn't cut any more without horribly disfiguring his face.

Rykert was referred to Virginia G. Piper Cancer Center Clinical Trials, which was starting a drug trial called the hedgehog-pathway trial. Doctors were using GDC-0449, which works by blocking the “hedgehog pathway” that produces a



Dr. Glen Weiss examines Jon Rykert during the Sacramento man's monthly checkup at the Virginia G. Piper Cancer Center in Scottsdale. MARK HENLE/THE REPUBLIC

SCREENING RESULTS

In May, during Skin Cancer Prevention Month, more than half of the 411 people who were screened at Scottsdale Healthcare were diagnosed with possible skin cancer or referred for a biopsy. Other findings:

- » 126 participants (30.66 percent) were at risk and had a presumptive diagnosis of pre-skin cancer.
- » 15 had a presumptive diagnosis of basal-cell carcinoma.
- » 3 (less than 1 percent) had a presumptive diagnosis of melanoma.
- » 9 (2.19 percent) had a presumptive diagnosis of squamouscell carcinoma.
- » 68 (16.5 percent) were referred to a physician for a follow-up biopsy.

Source: Virginia G. Piper Cancer Center at Scottsdale Healthcare.

known tumor-producing gene.

Final results of the study are still pending, but early indicators are that the drug shrank tumors in 18 of 33 patients.

Rykert, the father of six daughters and a son, called it a “miracle drug.”

“The drug I'm taking has cleared everything up,” he said. “And they've done ultrasounds, and they can't find any tumors growing anywhere.”

The doctors at Scottsdale Healthcare

and TGen say the significance of the drug is that people with advanced basal cell carcinoma will have a form of treatment when excising the tumor is no longer effective or possible because it has spread into the skin, bones and other tissues.

“Most of the time, people find a little spot on the skin, they go to the dermatologist and it's easily shaved off,” said Dr. Ramesh Ramanathan, medical director of the Virginia G. Piper Cancer Center Clinical Trials. “But for others, it just keeps coming back, usually on the face, and at one point you just can't keep cutting.”

FDA approval would provide more people with advanced basal cell carcinoma access to the drug.

“This form of treatment could save lives and prolong the quality of life for others,” said Dr. Glen Weiss, an assistant professor of TGen's Cancer and Cell Biology Division and director of thoracic oncology at Virginia G. Piper Cancer Center Clinical Trials.

Weiss said studies have shown the side effects are minimal and may include some hair and weight loss and loss of taste.

Scottsdale is in the early stages of testing the safety and effectiveness of GDC-0449 for treatment of other forms of cancer, including pancreatic.

Rykert said his cancer was at an all-time low before he began treatment in Scottsdale. His 26-year-old twin daughters have the same type of cancer, but milder forms of it.

“You couldn't ask for a better medical team,” he said. “They really do care; it's not just a job for them.”

ARIZONA SKIN-CANCER FACTS

» An estimated 1,460 Arizona residents were diagnosed with melanoma in 2009. Melanoma is responsible for about 75 percent of all skin-cancer deaths.

» The rate of new melanoma diagnoses is nearly 75 percent higher among men than women in Arizona.

» Coconino County has the highest rate of new melanoma diagnoses in the state — 54 percent higher than the state average.

» About 170 people in Arizona die of melanoma every year.

» Gila County has the highest melanoma death rate in the state — 70 percent higher than the national average.

Sources: A SunWise project with information from the Environmental Protection Agency and the Centers for Disease Control and Prevention.

DRUG'S ORIGIN

During the late 1950s in Idaho, farmers were noticing that mother sheep were giving birth to lambs with only one eye. A veterinarian figured out that when a pregnant sheep ate the California corn lily, it produced cyclops offspring. An 11-year-study by the U.S. Department of Agriculture later discovered a chemical in the plant, dubbed cyclopamine, stopped the development of the lamb's eye by turning certain genes on and off.

In the 1990s, a signaling pathway — a process that activates genes in the human body — was found in humans that took on the name “hedgehog pathway” because scientists studying this pathway in fruit flies noticed that if it was blocked during the development of the flies, they curled up and looked like hedgehogs.

Fast-forward a few decades, and cyclopamine was found to block the hedgehog pathway, which stopped abnormal cell growth in a number of cancers, including basal cell carcinoma. The study of the experimental drug by the Virginia G. Piper Cancer Center Clinical Trials in Scottsdale was dubbed the Hedgehog study. The experimental drug used in the study, based on the mechanism of action of cyclopamine, is called GDC-0449.