

Revolutionary drug could be new hope for adrenal cancer patients

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The TGen Clinical Research Services clinic is located in The Virginia G. Piper Cancer Center at Scottsdale Healthcare Shea Medical Center in Scottsdale, Arizona. TCRS is a strategic alliance between the Translational Genomics Research Institute (TGen) and Scottsdale Healthcare, facilitating laboratory bench-to-patient bedside application of new treatment discoveries for patients with cancer. Credit: Scottsdale Healthcare

TGen Clinical Research Services at Scottsdale Healthcare today announced the start of a clinical trial for a drug designed to combat adrenocortical carcinoma (ACC), a rare but deadly cancer that attacks the adrenal glands.

TCRS is a strategic alliance between the Translational Genomics Research Institute (TGen) and Scottsdale Healthcare.

Other than surgery, the only treatment for ACC is the exacting use of a

compound called mitotane, a chemical relative of DDT, which the U.S. banned as an insecticide in 1972.

TCRS clinicians hope the new compound, OSI-906, developed by OSI Pharmaceuticals Inc. of Melville, N.Y., will stop ACC tumor growth - perhaps even promote tumor shrinkage - without the toxic side effects of current chemotherapies. The trial will focus on patients with inoperable tumors who have relapsed or failed to respond to conventional therapies.

This clinical trial of OSI-906 is expected to last several years and include 135 patients, with 30-40 enrolled at TCRS. As there is no standard therapy available, two-thirds of the patients will receive the drug OSI-906 while one-third receives a placebo. Sites elsewhere in the U.S., as well as in Europe and Australia, are expected to enroll patients over the coming months.

"The trial is major step toward helping patients with ACC, who often face radical surgery as part of their treatment," says Dr. Michael J. Demeure, who will oversee the trial locally. Dr. Demeure is a TGen Senior Investigator and a Scottsdale Healthcare surgeon experienced in removing ACC tumors.

"It's a big operation requiring a large incision because these tumors can be the size of a football. Unfortunately many patients' tumors have spread so we can't remove it all, so new treatments are needed." said Dr. Demeure. "This unique partnership between Scottsdale Healthcare and TGen allows us to bring the newest and most promising treatments to patients with cancer right here in Arizona."

The adrenal glands are responsible for making several critical hormones, including cortisol, which the body needs in order to respond to stress and which helps to maintain normal blood sugar levels in children.

While use of mitotane in ACC patients reduces tumors, it also diminishes adrenal gland function, requiring patients to take hormone replacements for the rest of their lives. In addition, mitotane must be administered for at least three months in order to reach a therapeutic level. Even then, it has proved effective in about 22 percent of ACC cases. When given with other [chemotherapy](#) drugs, the effectiveness of mitotane may be improved, but patients often suffer debilitating side effects.

OSI-906 is an orally available small molecule IGF-1R inhibitor that blocks the chemical pathway that otherwise allows the ACC tumors to grow out of control. OSI-906 is expected to have minimal impact on the healthy tissue of the [adrenal glands](#) or their normal function.

"Being the first site in the world for [clinical trials](#) of this drug adds to the long list of 'firsts' for the Virginia G. Piper Cancer Center," said Mark Slater, Ph.D., vice president of research. "Scottsdale Healthcare's collaborations with world-class physicians and scientists are helping pave the way for exciting new cancer treatments to benefit patients with cancer everywhere."

Although ACC is very rare, affecting only one or two people per million, Dr. Demeure said developing new drugs against this orphan indication is worth the effort and expense.

"Patients with rare tumors have unique challenges. Often it is difficult for them to find a doctor who even knows about their disease," he said. "What we learn taking care of those patients with ACC could help us learn how to take care of others with rare tumors."

The clinical trial follows nearly 3 1/2 years of research at TGen, initiated through the efforts of patient advocate and ACC survivor, Mr. Troy Richards.

Richards, a Valley resident, has battled ACC since 1999. To combat what little research he saw being done on the disease, he began the Advancing Treatments for Adrenocortical Carcinoma (ATAC) fund, which helped finance the ACC Research Program at TGen.

"The ACC project at TGen has finally given those of us with the disease hope for better treatments, and maybe one day a cure," said Mr. Richards. "It is my hope that this program can serve as a model for other rare diseases, and that patients will realize they do have the power to make a difference."

Dr. Kimberly Bussey, a TGen Associate Investigator and Lead Investigator for TGen's Adrenocortical Carcinoma Research Program, said, "Troy brings a sense of urgency and a connection to the ACC patient community that made this trial possible. This is a huge accomplishment for the ACC Research Program at TGen and a great testament to what patient-advocated research can accomplish in a short period of time."

"We are eagerly awaiting the opening of this study" said Dr. Maqbool Halepota, an oncologist with the Palo Verde Hematology/Oncology group based at the Virginia G. Piper Cancer Center at Scottsdale Healthcare. "I firmly believe that targeted therapies are the future of cancer care, and our partnership with TCRS allows patients in the Phoenix area access to many innovative trials," Dr. Halepota added.

Source: Scottsdale Healthcare

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