

Clinical trial could lead to new bladder cancer drug

24 November 2015, by Nana Ohkawa



Dr. Charles Rosser, director of the UH Cancer Center's Clinical Trials Office

A bladder cancer drug tested in a University of Hawai'i Cancer Center clinical trial is getting closer to Food and Drug Administration (FDA) approval. The new drug, an interleukin 15 superagonist complex (ALT-803), combined with Bacillus Calmette-Guerin (BCG) is expected to be more effective for patients with non-muscle invasive bladder cancer, the most common type of bladder cancer.

"The last time the FDA approved a [drug](#) for [bladder cancer](#) was almost two decades ago," said Dr. Charles Rosser, director of the UH Cancer Center's Clinical Trials Office. "Bladder cancer treatment hasn't advanced very much; BCG has been the main drug used to treat the disease since the '80s. The science field has changed so much since then. We may finally be able to move the field forward and get better drugs to patients."

Phase II of the study was recently approved by the Institutional Review Board (IRB) and FDA. The first patient for Phase II was enrolled on October 15, 2015. The Phase II study will have about 124

participants, most of whom will be from Hawai'i. The goal of this phase is to show improved outcomes for cancer patients.

Said Dr. Rosser, "At least five other academic centers on the mainland are opening this clinical trial because of encouraging preclinical studies in addition to the Phase I clinical trial results. It is exciting because it started here in Hawai'i and other patients across the country, even across the world, may see positive results as well."

Phase I of the study with about 9 participants was completed in summer 2015. At least 20 percent of the participants were expected to have a recurrence of bladder cancer by now but, so far, no patients have. Overall, bladder cancer has a high recurrence rate of more than 50 percent.

Said Kailua resident Clark Morgan, a Phase I clinical trial participant, "I knew this drug had positive results in the lab, so I didn't hesitate to be a part of this clinical trial. I thought, well, I have bladder cancer, and my wife had breast cancer about 7 years ago, so she said we have to do what we can. I thought it was convenient and that I could stay in Hawai'i to get this treatment. I don't know if I would have gone if it was on the mainland."

Nationally there are 74,000 new cases of bladder cancer and an estimated 16,000 deaths every year, according to the National Cancer Institute. It is ranked in the top five cancers for men in the U.S. The disease occurs more often in men than women.

Phase I showed that the trial was well-tolerated, and also demonstrated the recommended dose to be tested in Phase II. Researchers aim to get the ALT-803 drug created by Altor BioScience Corporation (Miramar, Florida) FDA approved.

Provided by University of Hawaii at Manoa

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