GW Cancer Center expands clinical trial offerings for cutaneous squamous cell carcinoma

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The Cutaneous Oncology Program at the George Washington University (GW) Cancer Center was selected as the first global site for a clinical trial for patients with high-risk cutaneous squamous cell carcinoma. This designation highlights the GW Cancer Center's growing regional and global reputation for treating patients with advanced squamous cell carcinoma, the second most common form of skin cancer behind basal cell carcinoma. The study, sponsored by Regeneron, will examine outcomes for patients treated with Libtayo (cemiplimab)—an immunotherapy treatment—prior to surgery and radiation therapy.

In June 2019, the GW Cancer Center was selected as the first global site for a related clinical trial on the effectiveness of Libtayo given after primary surgery and radiation therapy. This new study will focus on the impact of Libtayo on tumors prior to surgery, with the goal to help shrink the tumor and potentially prevent the cancer from returning or metastasizing. Preliminary results from a similar trial at MD Anderson Cancer Center showed promising responses to pre-surgical checkpoint inhibitors in patients with advanced cutaneous squamous cell carcinoma of the head and neck.

"By being selected as the first global site for not one, but two clinical trials in 2019, we are continuing to grow our reputation as one of the most innovative programs for patients with advanced cutaneous squamous cell carcinoma," said Vishal A. Patel, MD, FAAD, FACMS, director of the Cutaneous Oncology Program at the GW Cancer Center and principal investigator of the study. "Our growth means even more patients in our region will have access to the latest potentially promising treatments and therapies."

The phase II trial is intended to investigate the safety and effectiveness of Libtayo in helping reduce the size of tumors and prevent recurrence in high risk cutaneous squamous cell carcinoma, particularly when given early. The study, currently only available at the GW Cancer Center, is estimated to enroll over 75 participants.

"This clinical trial fits clearly within our mission to drive transformational research and personalized therapy," said Eduardo M. Sotomayor, MD, Dr. Cyrus Katzen Family Director of the GW Cancer Center and professor of medicine at the GW School of Medicine and Health Sciences. "Our role as an academic cancer center means we are uniquely positioned to get the latest therapies from bench to bedside, and expanding our clinical trial offerings highlights our commitment to advancing both cancer research and patient care."

Libtayo was approved by the U.S. Food and Drug Administration in September 2018 as cemiplimab-rwlc to treat patients with metastatic cutaneous squamous cell carcinoma or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation. The immunotherapy treatment is a fully-human monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1) and was the first treatment approved and available in advanced cutaneous squamous cell carcinoma in the U.S. Current treatment options for the disease include surgery, such as Mohs micrographic surgery, radiation therapy, and systemic chemotherapy for metastatic disease. Libtayo is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

"Clinical investigations like this one are critical to expanding the treatment options available to patients," said Mitchell Smith, MD, Ph.D., associate center director for clinical investigations at the GW

Cancer Center. "By examining neoadjuvant applications of immunotherapy drugs like Libtayo, the hope is that patients will be able to be treated with less invasive surgeries or avoid surgery altogether."

The Cutaneous Oncology Program at the GW Cancer Center brings together dermatologists; dermatologic surgeons; medical, surgical, and radiation oncologists; and dermato-pathologists to provide comprehensive and personalized skin cancer care to patients. The program also houses the Supportive Oncodermatology and Cutaneous T-Cell Lymphoma multidisciplinary clinics.

The potential use of Libtayo in neoadjuvant cutaneous squamous cell carcinoma is investigational, and its safety and efficacy have not been evaluated by any regulatory authority for this use.

More information: cancercenter.gwu.edu/clinical-… ous-oncology-program

Provided by George Washington University