RESULTS FROM LATE STAGE BLADDER CANCER CLINICAL TRIAL CONDUCTED BY SUO-CTC ARE PUBLISHED IN THE LANCET ONCOLOGY



Investigational Treatment Option May Offer New Hope for Patients

NEWS RELEASE BY SOCIETY OF UROLOGIC ONCOLOGY

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A breakthrough therapy discovered during Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC) Phase 2 and 3 trials was published by The Lancet Oncology. The Lancet Oncology is an authoritative forum for key opinion leaders across medicine, government, and health systems to influence clinical practice, explore global policy, and inform constructive, positive change worldwide. The treatment, currently with the U.S. Food and Drug Administration (FDA) has the potential to offer physicians a new option in treating bladder cancer. It also has the potential to offer hope to those suffering from the disease.

The Lancet Oncology paper, co-authored by Dr. Colin Dinney, Co-Founder of the SUO-CTC, provides significant details about the trial and its encouraging findings. The landmark U.S. clinical trial evaluated the investigational gene therapy, nadofaragene firadenovec.

"As explained in our paper, the trials we conducted were designed to assess patients who suffer from high grade non-muscle-invasive bladder cancer and were unresponsive to previous treatments (BCG therapy). In the absence of such therapies, many of these patients face complete removal of their bladder due to the aggressive nature of the disease," explained Dr. Dinney. "The development and testing of nadofaragene firadenovec is a prime example of an effective collaboration between the SUO-CTC and Pharma to develop the novel therapeutic as an alternative to surgical bladder removal."

During the Phase 2 and Phase 3 clinical trials conducted by the SUO-CTC, the treatment was administered to patients via a catheter, directly into the bladder. It is believed to work by helping the body produce high quantities of a protein that fights bladder cancer.

"One of the advantages of nadofaragene firadenovec is that it has a favorable safety profile. We have demonstrated consistent efficacy in multiple trials. The other great advantage is the convenient treatment schedule," Dr. Dinney continued. "With nadofaragene firadenovec, patients receive one dose every three months. This makes it very appealing to both physicians and patients."

"We believe the important clinical findings highlighted in The Lancet Oncology with this novel gene therapy may fulfill a significant unmet need for patients and have the potential to be practice-changing," said Vijay Kasturi, MD, Vice President of Medical Affairs at FerGene, a gene therapy company committed to revolutionizing the treatment of bladder cancer. "We are extremely grateful to the investigators, the patients who participated in the study, and the SUO-CTC for the important findings highlighted in this publication."

Nearly 68,000 people in the United States are impacted by bladder cancer every year, making it one of the most common cancers. It also one of the deadliest cancers that will claim close to 18,000 lives in the US this year alone.

In addition to bladder cancer trials, the SUO-CTC also collaborates in partnership with pharmaceutical and biotechnology companies to develop and conduct trials for prostate cancer and renal cancer.

Created, owned, and operated by its members, the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC) is a clinical research investigator network of more than 400 members from more than 200 clinical sites in the U.S. and Canada. This national alliance of leading academic and community based uro-oncologists is committed to furthering urology research. The SUO-CTC is a registered 501c3 not-for-profit corporation and has a cooperative relationship with the Society of Urologic Oncology (SUO).

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Please visit http://www.suoctc.org

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