Phase II Trial Shows Favorable Response for Patients Receiving Combination Therapy With SurVaxM

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CHICAGO (PRWEB) June 02, 2019 -- With their phase II study in patients with aggressive brain cancer now completed, the developers of the cancer immunotherapy SurVaxM are sharing research results at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO), reporting that combination therapy with the vaccine was more effective than standard therapy for nearly all patients. The meeting, which continues through June 4 at McCormick Place in Chicago, Illinois, is the largest clinical cancer research meeting in the world.

SurVaxM was developed at Roswell Park Comprehensive Cancer Center by Robert Fenstermaker, MD, Chair of Neurosurgery, and Michael Ciesielski, PhD, Assistant Professor of Neurosurgery. The vaccine is a new and unique cancer immunotherapy designed to stimulate a multifaceted immune response targeting survivin, a tumor-survival antigen not generally present in nonmalignant cells.

In this five-center, single-arm phase II clinical trial (NCT identifier no. 024455557), 63 patients with newly diagnosed glioblastoma (nGBM), median age 60, were followed for safety, six-month progression-free survival, 12-month overall survival and immunologic response. All patients underwent standard treatment, involving craniotomy, radiation and treatment with temozolomide both before and after surgery. Immune response was assessed by detection of a survivin-specific antibody and CD8+ T-cell levels.

The team reports that, compared to a historical analysis of patients receiving standard therapy alone, combination therapy with SurVaxM generated encouraging efficacy and immunogenicity in patients with newly diagnosed glioblastoma, with minimal toxicity or side effects. The vast majority of patients — 96.8% — did not experience disease progression within six months of treatment, and 93.5% were alive a year after diagnosis, compared to expected 65% survival based on historical comparisons.

“We saw significant increase in both progression-free and overall survival, which is noteworthy in patients with such a notoriously aggressive and treatment-resistant disease,” says Dr. Fenstermaker, senior author on the study.

“We were especially pleased to see that even patients with poor prognostic factors like high levels of survivin responded well to this combination of standard therapy plus SurVaxM,” adds Dr. Ciesielski, who will present these findings in a poster presentation during the ASCO Annual Meeting.

The results will also be highlighted in a poster discussion by first author Manmeet Ahluwalia, MD, Miller Family Endowed Chair in NeuroOncology at Cleveland Clinic. Researchers from Beth Israel Deaconess Medical Center, Dana-Farber Cancer Institute/Harvard Medical School and Massachusetts General Hospital also contributed to this research.
Glioblastoma is the most common form of brain cancer in adults, and also the most aggressive. Median survival for patients treated with standard therapy is 14.7 months.

SurVaxM was awarded orphan drug designation by the U.S. Food and Drug Administration (FDA) in 2017. New studies incorporating SurVaxM are expected to open at both Cleveland Clinic and Roswell Park in the coming months.

Drs. Fenstermaker and Ciesielski gratefully acknowledge donations to Roswell Park in support of their work.

Dr. Ciesielski will also give an invited presentation about SurVaxM June 3 during the 2019 BIO International Convention in Philadelphia (session ID 537706) on behalf of MimiVax LLC, an early-phase Roswell Park spinoff company formed to develop the vaccine. Drs. Ciesielski and Fenstermaker are co-founders and equity shareholders in MimiVax.

ASCO 2019 Presentation Details:

SurVaxM with standard therapy in newly diagnosed glioblastoma: Phase II trial update

Abstract 2016

Poster presentation:
Presenting author: Michael Ciesielski, PhD, Roswell Park Comprehensive Cancer Center
Time/date: Sunday, June 2, from 8 a.m. to 11 a.m. CDT
Location: Hall A
Session: Central Nervous System Tumors
Poster board: 205
Poster discussion session:
Presenting author: Manmeet Ahluwalia, MD, Taussig Center Institute, Cleveland Clinic
Time/date: Sunday, June 2, from 4:30 p.m. to 6 p.m. CDT
Location: Room S404
Session: Central Nervous System Tumors

This release is also available on the Roswell Park website: https://www.roswellpark.org/media/news/phase-ii-trial-shows-favorable-response-patients-receiving-combination-therapy-survaxm.

Roswell Park Comprehensive Cancer Center is a community united by the drive to eliminate cancer’s grip on humanity by unlocking its secrets through personalized approaches and unleashing the healing power of hope. Founded by Dr. Roswell Park in 1898, it is the only National Cancer Institute-designated comprehensive cancer center in Upstate New York. Learn more at www.roswellpark.org, or contact us at 1-800-ROSWELL (1-800-767-9355) or ASKRoswell@RoswellPark.org.
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