Ziopharm Oncology Completes Enrollment of Phase 2 Trial Evaluating Controlled IL-12 in Combination with Libtayo® in Patients with Glioblastoma

June 22, 2020

BOSTON, June 22, 2020 (GLOBE NEWSWIRE) -- Ziopharm Oncology, Inc. (“Ziopharm” or “the Company”) (Nasdaq:ZIOP) today announced that 36 subjects have been enrolled in the phase 2 clinical trial evaluating Ad-RTS-hIL-12 with veledimex (Controlled IL-12) in combination with the PD-1 inhibitor Libtayo® (cemiplimab-rwlc) for the treatment of recurrent or progressive glioblastoma (rGBM) in adults. Subjects in this multi-center trial were enrolled from seven hospitals specializing in the treatment of brain cancers across the United States.

“Achieving this milestone reinforces the critical need for new treatments for rGBM and highlights the optimism from the clinical community for the potential of Controlled IL-12,” said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm. “I want to thank the clinicians and healthcare workers for their dedication and commitment to oncology patient care which has allowed us to continue advancing the development of our Controlled IL-12 program during these challenging times.”

Ziopharm’s Controlled IL-12 platform is an investigational gene therapy designed to induce and control the production of human interleukin 12 (hIL-12), a master-regulator of the immune system. In the setting of rGBM, the Company is leveraging the anti-tumor effects for Controlled IL-12 as a monotherapy and in combination with PD-1 inhibitors. Clinical data supporting the combination of Controlled IL-12 and a PD-1 inhibitor were initially published in *Science Translational Medicine* (Chiocca et al., 2019). Data from serial biopsies in patients with rGBM revealed that Controlled IL-12 results in the sustained influx of activated T cells and upregulation of PD-1 expression, providing a compelling rationale for this combination. Recently, additional data from a phase 1 trial were presented at the American Society of Clinical Oncology (ASCO) 2020 virtual meeting showing Controlled IL-12 in combination with a PD-1 inhibitor had a favorable safety profile and preliminary signs of anti-tumor efficacy.

Rimas Lukas, M.D., Associate Chief of the Neuro-Oncology Division, Northwestern University Feinberg School of Medicine and the Lou and Jean Malnati Brain Tumor Institute, and investigator in the phase 2 study, added, “The data presented at ASCO earlier this year demonstrated encouraging anti-tumor effects of combining Controlled IL-12 with a PD-1 inhibitor. We look forward to the results of this ongoing phase 2 trial that will inform whether Controlled IL-12 in combination with cemiplimab could represent a potential treatment option for patients with recurrent glioblastoma, a devastating brain cancer for which there is a significant unmet need for new effective therapies.”

The open-label, single-arm phase 2 trial (NCT04006119) is designed to examine Controlled IL-12 in combination with cemiplimab in 36 patients with rGBM, with the primary endpoints being safety and efficacy. Patients with rGBM scheduled for resection, who have not been treated previously with immune checkpoint inhibitors, received Ad-RTS-hIL-12 intratumorally at the time of surgical resection plus 20 mg of veledimex, an oral activator of Ad-RTS-hIL-12, daily for 14 days. Patients will also receive cemiplimab intravenously (350 mg) every three weeks until documented progression or withdrawal from the study. Trial investigators may enroll additional patients currently in screening.

In November 2018, Ziopharm and Regeneron entered a clinical supply agreement to evaluate combination therapy of Ziopharm’s Controlled IL-12 with Regeneron’s PD-1 antibody cemiplimab to treat patients with rGBM.

About Ziopharm Oncology, Inc.
Ziopharm is developing non-viral and cytokine-driven cell and gene therapies that weaponize the body’s immune system to treat the millions of people globally diagnosed with a solid tumor each year. With its multiplatform approach, Ziopharm is at the forefront of immuno-oncology with a goal to treat any type of solid tumor. Ziopharm’s pipeline is built for commercially scalable, cost effective T-cell receptor T-cell therapies based on its non-viral *Sleeping Beauty* gene transfer platform, a precisely controlled IL-12 gene therapy, and rapidly manufactured *Sleeping Beauty*-enabled CD19-specific CAR-T program. The Company has clinical and strategic partnerships with the National Cancer Institute, The University of Texas MD Anderson Cancer Center and others. For more information, please visit www.ziopharm.com.

Forward-Looking Statements Disclaimer
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding the progress, design and timing of the Company's research and development programs. Although Ziopharm’s management team believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Ziopharm, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, changes in our operating plans that may impact our cash expenditures, the uncertainties inherent in research and development, future clinical data and analysis, including whether any of Ziopharm’s product candidates will advance further in the preclinical research or clinical trial process, including receiving clearance from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies to conduct clinical trials and whether and when, if at all, they will receive final approval from the U.S. FDA or equivalent foreign regulatory agencies and for which indication; the strength and enforceability of Ziopharm’s intellectual property rights; competition from other pharmaceutical and biotechnology

companies as well as risk factors discussed or identified in the public filings with the Securities and Exchange Commission made by Ziopharm, including those risks and uncertainties listed in Ziopharm's Quarterly Report on Form 10-Q filed by Ziopharm with the Securities and Exchange Commission. We are providing this information as of the date of this press release, and Ziopharm does not undertake any obligation to update or revise the information contained in this press release whether as a result of new information, future events or any other reason.

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Source: ZIOPHARM Oncology Inc