Ziopharm Oncology Doses First DIPG Patient in Phase 1/2 Trial of Controlled IL-12 for the Treatment of Pediatric Brain Tumors

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BOSTON, July 08, 2020 (GLOBE NEWSWIRE) -- Ziopharm Oncology, Inc. (“Ziopharm” or “the Company”) (Nasdaq:ZIOP) today announced that the first patient with diffuse intrinsic pontine glioma (DIPG) has been dosed in its phase 1/2 study of Ad-RTS-hIL-12 with veledimex (Controlled IL-12) for the treatment of pediatric brain tumors.

“We are pleased to report that this young child has tolerated the dosing regimen well,” said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm. “Working with our colleagues at Northwestern University and Lurie Children’s Hospital, we continue to monitor this patient’s progress and are evaluating additional patients for enrollment in Chicago and at the other trial sites. For Ziopharm, this trial represents an additional clinical path for of Controlled IL-12, beyond the ongoing studies in recurrent glioblastoma (rGBM).”

Stewart Goldman, M.D., Division Head Hematology-Oncology, Neuro-Oncology & Stem Cell Transplantation at Lurie Children's and investigator in the study, added, “One of the hallmark characteristics of DIPG is that immune cells cannot access the tumor, yet the microenvironment is not immunosuppressive. Therefore, driving T cells into this tumor could change the outcome for children with this lethal disease. Ziopharm’s data evaluating Controlled IL-12 in rGBM demonstrates that there is a sustained infiltration of activated T cells, turning “cold” tumors “hot” for months after veledimex dosing is finished. Extensive experience, as well as encouraging survival data associated with treating rGBM in adults, underscores our desire to evaluate Controlled IL-12 in children with gliomas, who currently lack viable treatment options.”

The phase 1/2 trial (NCT03330197) is designed to evaluate the safety and tolerability of a single intratumoral injection of Ad-RTS-hIL-12 given with up to 14 days of oral veledimex in children with gliomas. Up to 12 patients may be enrolled in phase 1 of the study, which is being conducted at leading pediatric cancer centers across the United States, including the Dana-Farber Cancer Institute in Boston and the University of California in San Francisco.

About DIPG
In children, the incidence of brain cancer is approximately 4.84 per 100,000, according to the National Cancer Institute. Glioma in the pontine region of the brain, or DIPG, accounts for approximately 10-15 percent of all cases of pediatric brain tumors, with about 150-300 new diagnoses per year in the United States.[1] Median survival ranges from 8-11 months.[2] There are no curative options.

About Controlled IL-12 (Ad-RTS-hIL-12 plus veledimex)
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. The Company has treated more than 175 patients, including more than 125 patients with rGBM, with Ad-RTS-hIL-12 plus veledimex and administered more than 1,300 doses of veledimex across three types of solid tumors, building a significant safety profile, mechanistic dataset and evidence of anti-tumor effects.

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 and timing of the Company's research and development programs, including the anticipated dates for the initiation, completion and readouts of its clinical trials and the Company’s expectations regarding the number of patients in its clinical trials. 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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[1] Source: DIPG.org. Accessed June 30, 2020.

[2] Hargrave D, Bartels U, Bouffet E. Diffuse brainstem glioma in children: critical review of clinical trials. Lancet Oncol. 2006 Mar;7(3):241-8.

Source: ZIOPHARM Oncology Inc