



Ziopharm Oncology Announces FDA Clearance of IND for Sleeping Beauty TCR-T Cell Therapy Trial at NCI

June 11, 2019

– Positions Ziopharm to be first company to bring non-viral TCR-T into the clinic –

– Company to host informational conference call June 12, 2019 at 8:30 am ET –

BOSTON, June 11, 2019 (GLOBE NEWSWIRE) -- [Ziopharm Oncology](#), Inc. ("Ziopharm" or "the Company") (Nasdaq:ZIOP) announced that the investigational new drug (IND) application submitted by the National Cancer Institute (NCI) has received clearance from the U.S. Food and Drug Administration (FDA) for a clinical trial in solid tumors to evaluate T-cell receptor (TCR) T-cell therapy utilizing Ziopharm's *Sleeping Beauty* platform.

"This study is the result of extensive work by Dr. Steven Rosenberg and his team at the NCI, including Dr. Drew Deniger, to harness our *Sleeping Beauty* non-viral gene transfer technology to express neoantigen-specific T-cell receptors (TCRs)," said Dr. Laurence Cooper, Chief Executive Officer of Ziopharm. "This important regulatory milestone combined with our recent license from the NCI for a library of TCRs reactive to mutations, or neoantigens, within KRAS, p53 and EGFR hotspots for use with the *Sleeping Beauty* platform, underscores the broad scope and potential of our TCR-T program. In collaboration with the NCI, we are now in position to be the first company to bring non-viral TCR-T into the clinic."

Ziopharm and the NCI are partnered in a cooperative research and development agreement (CRADA), under the direction of Dr. Rosenberg, Chief of the Surgery Branch of the NCI, supporting clinical work to evaluate a non-viral approach to manufacturing TCR-T with the *Sleeping Beauty* platform that target solid tumors. With this approach, T cells can be genetically modified to express multiple, tumor-specific TCRs, which Ziopharm believes will be foundational technology to successfully targeting and treating metastatic solid tumors.

The Company will host an informational webcast and conference call to provide additional context related to its non-viral TCR-T program on Wednesday, June 12, at 8:30 am ET. The call can be accessed by dialing 1-844-309-0618 (U.S. and Canada) or 1-661-378-9465 (international). The passcode for the conference call is 3782556. To access the live webcast or the subsequent archived recording, visit the "Investors" section of the Ziopharm website at www.ziopharm.com. The webcast will be recorded and available for replay on the Company's website for two weeks.

About Ziopharm Oncology, Inc.

Ziopharm Oncology is an immuno-oncology company focused on developing end-to-end cost-effective solutions using its non-viral *Sleeping Beauty* platform for TCR and CAR T-cell therapies and immune-stimulating gene therapy with Controlled Interleukin 12 (IL-12). The *Sleeping Beauty* platform genetically modifies T cells with DNA plasmids to express T-cell receptors (TCRs) to target specific antigens in solid tumors and chimeric antigen receptors (CARs) to target CD19 in blood cancers with the Company's very rapid T-cell manufacturing process. The *Sleeping Beauty* platform is being advanced in collaboration with the National Cancer Institute, The University of Texas MD Anderson Cancer Center and Eden BioCell. The Company also is developing its Controlled IL-12 platform, or Ad-RTS-hIL-12 plus veledimex, as monotherapy and in combination with immune checkpoint inhibitors to treat brain cancer, including in collaboration with Regeneron Pharmaceuticals.

Note Regarding Forward-Looking Statements

This news 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 potential clinical benefits of its TCR-T program in treating patients and the progress and timing of the development of Ziopharm's and the NCI's research and development programs, including the timing for the initiation and completion of 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 and maintaining 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 most recent 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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