Ziopharm Oncology Reports Second Quarter 2019 Financial Results

August 8, 2019

– FDA Cleared IND for Phase 1 Trial of Sleeping Beauty *TCR-T cell therapy for patients with solid tumors at the National Cancer Institute (NCI) –*
– Exclusive license from NCI for library of T-cell receptors (TCRs) targeting neoantigens in the hotspots KRAS, p53 and EGFR –
– Balance sheet strengthened with $45 million in proceeds from early warrant exercise –
– NCI's Dr. Drew Deniger to direct TCR program; Sath Shukla named CFO –
– Company to host conference call and webcast today at 8:30 a.m. ET –

BOSTON, Aug. 08, 2019 (GLOBE NEWSWIRE) -- Ziopharm Oncology, Inc. ("Ziopharm" or the "Company") (Nasdaq: ZIOP), a clinical stage immuno-oncology company developing next generation cell and gene therapies, today announced its financial results for the second quarter ended June 30, 2019, and provided an update on the Company's recent activities.

"We have made significant advancements in our programs during the second quarter. The FDA cleared the IND for the first non-viral, neoantigen-specific TCR-T cell therapy at the NCI using our *Sleeping Beauty* system and we announced an exclusive license to an expansive library of TCRs against neoantigens in three of the most important hotspot families," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm. "In our Controlled IL-12 program, we completed enrollment of the third dosing cohort in our phase 1 combination trial with nivolumab and initiated a phase 2 combination trial with Regeneron's Libtayo ®. Finally, we refined our plans for the third-generation *Sleeping Beauty* CD19-specific CAR-T phase 1 trial at MD Anderson Cancer Center, which we continue to expect to commence later this year."

David Mauney, M.D., President of Ziopharm, added, "As our clinical programs continue to advance, we have strengthened our balance sheet and expanded the breadth and depth of our corporate leadership. We are proud to welcome Sath Shukla and Dr. Drew Deniger to our leadership team and Heidi Hagen to our Board of Directors. We are grateful that through the support of key shareholders who exercised their existing warrants several years prior to expiration, we added $45 million to our treasury to provide us with cash into the first half of 2021, which we expect will allow us to see data readouts in the three programs."

Corporate Updates

Since the beginning of the second quarter, Ziopharm has announced positive corporate developments regarding expansion of the management team and strengthening of the company's balance sheet.

- **Balance sheet strengthened with $45 million:** A group of Ziopharm shareholders, led by MSD Partners, L.P., exercised their existing warrants to purchase common stock, which resulted in gross proceeds of approximately $45 million. We expect this additional capital is sufficient to fund operations into 2021 and provide visibility into important clinical data milestones for Ziopharm's TCR-T, CAR-T and Controlled IL-12 programs.

- **Sath Shukla named CFO:** With 20 years of strategic corporate and financial leadership experience, Mr. Shukla joins as Chief Financial Officer from Vertex Pharmaceuticals, where he was most recently Vice President and global Head of Corporate Finance, directing financial planning, analysis and budgeting, and leading the annual long-range planning process encompassing Vertex's entire portfolio and operations across more than 30 countries.

- **NCI's Dr. Drew Deniger to Direct TCR-T Cell Therapy Program:** In early July, Ziopharm announced that Dr. Deniger was hired from the NCI to lead Ziopharm's non-viral T-cell program targeting neoantigens for personalized immunotherapy of solid tumors. Dr. Deniger worked under Dr. Steven Rosenberg at the NCI and is a recognized leader in the identification of TCRs targeting neoantigens. Dr. Deniger has a track record of helping to advance innovative immunotherapy approaches into the clinic and has years of expertise with the *Sleeping Beauty* system.

- **Heidi Hagen joins Board of Directors:** In June, Ziopharm appointed Heidi Hagen, an experienced and entrepreneurial biotechnology operations executive, to the Company's board of directors. The addition of Ms. Hagen represented the fifth new board member for Ziopharm in the past year.

Program Updates

Sleeping Beauty TCR-T Therapies

The Company is using its *non-viral gene transfer technology* to implement personalized T-cell therapy targeting solid tumors with TCRs. Under a Cooperative Research and Development Agreement (CRADA), the NCI is initiating a clinical trial to treat patients with metastatic/advanced solid tumors using the Company's *Sleeping Beauty* transposon/transposase platform to genetically modify patient-derived T cells with TCRs to target patient-specific neoantigens.

- **FDA Clearance of IND for *Sleeping Beauty* TCR-T cell therapy**: In June, Ziopharm announced that the investigational new drug (IND) application submitted by the NCI had received clearance from the U.S. Food and Drug Administration (FDA) for a clinical trial in solid tumors to evaluate TCR T-cell therapy utilizing Ziopharm's *Sleeping Beauty* platform. Under the direction of Steven Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI, and his team, the site is completing the internal processes for enrollment, while working to detect neoantigens to be targeted, isolating the TCRs and identifying patients for the trial.

- **Exclusive License with NCI to Identify and Use TCRs Targeting Neoantigens for Cancer with *Sleeping Beauty* Platform:** In May, Ziopharm announced an exclusive license agreement with NCI for intellectual property for the development and commercialization of cell therapies for cancer. The scope of the license includes a library of TCRs against neoantigens in hotspots including mutated KRAS, p53 and EGFR for use with transposons. The license also includes technologies to enhance manufacturing capabilities for clinical-grade T cells (referred to as TCR-T) through the *Sleeping Beauty* platform.

Sleeping Beauty CAR-T Therapies

Ziopharm is advancing the *Sleeping Beauty* platform for the rapid personalized manufacture (RPM) of CAR-T cells, co-expressing membrane-bound interleukin-15, or mbIL15, with a safety switch, enabling T cells to be infused within two days after genetic modification. This work on our third-generation *Sleeping Beauty* technology is undertaken **in collaboration with MD Anderson Cancer Center in the United States and in Greater China through a joint venture, Eden BioCell.**

- **Third-generation phase 1 trial for RPM of *Sleeping Beauty* CD19-specific CAR-T with mbIL15 expected to begin later this year:** The Company anticipates beginning a phase 1 trial at MD Anderson Cancer Center in the second half of this year, leveraging the Company's RPM to produce T cells in two days or less after gene transfer. The Company has prioritized a new clinical trial infusing donor-derived allogeneic RPM CAR-T in patients who relapse after bone marrow transplantation to complement its autologous efforts targeting CD19, thereby providing a suite of CAR-T technologies to address the continuum of patients with refractory $CD19^+$ malignancies.

- **Eden BioCell to advance third-generation *Sleeping Beauty* CD19-specific CAR-T for Greater China**: With TriArm Therapeutics, a Panacea Venture Healthcare backed company, Eden BioCell was formed as a joint venture to develop and commercialize *Sleeping Beauty*-generated CD19-specific CAR-T in Greater China using the RPM technology. Recruitment of staff and buildout of facilities is accelerating, and the Eden BioCell team has begun meetings with potential hospital sites and their clinical teams.

Controlled IL-12

Ziopharm is developing its Controlled IL-12 platform, or Ad-RTS-hIL-12 plus veledimex, to control the production of human interleukin 12 (hIL-12) which activates the immune system to recruit and sustain cancer-fighting T cells within solid tumors. Ziopharm is advancing Ad-RTS-hIL-12 plus veledimex for the treatment of recurrent glioblastoma multiforme (rGBM) as a monotherapy and in combination with immune checkpoint inhibitors.

- **Enrollment completed in third cohort of combination study with OPDIVO® (nivolumab):** Ziopharm announced in June that it had completed enrollment in three dosing cohorts in its phase 1 study of adult patients with rGBM to evaluate a single dose of Ad-RTS-hIL-12 plus daily veledimex in combination with OPDIVO, an immune checkpoint inhibitor against programmed death-1 (PD-1). Based on a favorable safety profile, investigators from this multi-center trial indicated interest in expanding the study and the Company now expects to enroll up to 12 additional patients at the highest dosing level.

- **Phase 2 combination trial with Regeneron's Libtayo® (cemiplimab-rwlc) initiated in June**: The Company, in collaboration with Regeneron Pharmaceuticals, initiated a phase 2 trial to evaluate Ad-RTS-hIL-12 plus veledimex in combination with Regeneron's PD-1 antibody Libtayo to treat patients with rGBM. Enrollment for this study has commenced, as the Company expects to enroll about 30 patients at approximately 10 sites.

- **Positive clinical data presented at 2019 ASCO Annual Meeting:** New interim analyses of clinical data from two ongoing substudies in its Controlled IL-12 platform, both as monotherapy and in combination with OPDIVO, were presented at ASCO in June. Additional updates are expected later this year.

- **FDA grants Fast Track status to Controlled IL-12 program:** Ziopharm announced in April that FDA granted Fast Track designation for its Controlled IL-12 program for the treatment of rGBM in adults.

Second Quarter 2019 Financial Results

- Net loss applicable to the common shareholders for the second quarter of 2019 was $14.6 million, or $(0.09) per share, compared to a net loss of $17.5 million, or $(0.12) per share, for the second quarter of 2018. The change in net loss to common shareholders resulted primarily from the elimination of approximately $5.5 million of dividends to preferred shareholders caused by the forfeiture and return of all of the Company's Series 1 preferred stock in October 2018, along with the changes in research and development expenses and general and administrative expenses noted below.
- Research and development expenses were $10.0 million for the second quarter of 2019, compared to $7.5 million for the second quarter of 2018. The increase in research and development expenses for the three months ended June 30, 2019 is primarily due to milestone costs under our patent license agreement with the NCI and increased nonclinical research and development to support our Cell Therapy programs. For additional context, research and development expenses in the first quarter of 2019 were $9.5 million.
- General and administrative expenses were $4.8 million for the second quarter of 2019, compared to $4.9 million for the second quarter of 2018. For additional context, general and administrative expenses in the first quarter of 2019 were $4.1 million.
- The Company ended the quarter with unrestricted cash resources of approximately $43.6 million.
- In addition, a prepayment of approximately $24.2 million remains for programs to be conducted by the Company at MD Anderson Cancer Center under the current Research and Development Agreement.
- As announced on July 29, 2019, the company raised approximately $45 million through the exercise of existing warrants. The Company believes its current resources will be sufficient to fund its planned operations into the first half of 2021.

– Financial Tables Follow –

ZIOPHARM Oncology, Inc.
Statements of Operations
(in thousands except share and per share data)
(unaudited)

	Three Months Ended June 30, (unaudited)	
	2019	**2018**
Collaboration revenue	$ -	$ -
Operating expenses:		
Research and development	9,998	7,489
General and administrative	4,755	4,889
Total operating expenses	14,753	12,378
Loss from operations	(14,753)	(12,378)
Other income (expense), net	133	164
Change in fair value of derivative liabilities	-	183
Net loss	(14,620)	(12,031)
Preferred stock dividends	-	(5,462)
Net Income (loss) applicable to common stockholders	$ (14,620)	$ (17,493)
Basic and diluted net loss per share	$ (0.09)	$ (0.12)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	160,789,272	141,017,898

ZIOPHARM Oncology, Inc.
Balance Sheet Data
(in thousands)
(unaudited)

	June 30, 2019	December 31, 2018
Cash and cash equivalents	43,563	61,729
Working capital	55,459	74,802
Total assets	73,173	95,051
Total stockholders' equity	61,995	85,564

Conference Call and Webcast

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 8279471. 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 TCRs to target specific antigens in solid tumors and a CAR to target CD19 in blood cancers with the Company's 3 rd generation T-cell manufacturing process, termed "rapid personalized manufacture". 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.

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 Company's business and strategic plans, the availability of cash resources, 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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