Ziopharm Oncology Reports Third Quarter 2019 Financial Results

November 7, 2019

– Phase 2 trial of Sleeping Beauty TCR-T cell therapy for patients with solid tumors initiated at the National Cancer Institute (NCI) –

– New agreement with MD Anderson Cancer Center to expand library of T-cell receptors (TCRs) targeting neoantigens; Enables new clinical trials –

– Balance sheet strengthened in Q3; cash into H1 2021 –

– Company to host conference call and webcast today at 4:30 p.m. ET –

BOSTON, Nov. 07, 2019 (GLOBE NEWSWIRE) -- Ziopharm Oncology, Inc. ("Ziopharm" or the "Company") (Nasdaq: ZIOP), today announced its financial results for the third quarter ended September 30, 2019, and provided an update on the Company's recent activities.

"Our company took dramatic steps forward in the past quarter, in particular with our TCR-T platform," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm. "The NCI advanced the TCR program using our *Sleeping Beauty* platform into a phase 2 trial and our new agreement with MD Anderson accelerates expansion of our TCR library and sets the foundation for two new clinical trials to be conducted there by Ziopharm. Our confidence surges as we have partnered with these leading institutions in tackling the massive, untapped market in solid tumors."

Program Updates

Sleeping Beauty TCR-T

The Company is using its *non-viral gene transfer technology* to implement personalized T-cell therapy targeting solid tumors with neoantigen-specific TCRs. Under a Cooperative Research and Development Agreement (CRADA), the NCI is undertaking a phase 2 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.

- **Phase 2 *Sleeping Beauty* TCR-T cell therapy trial at NCI**: In recent weeks, the NCI has provided details of the initiated clinical trial in solid tumors to evaluate TCR T-cell therapy utilizing Ziopharm's *Sleeping Beauty* platform: A Phase 2 Study Using the Administration of Autologous T-Cells Engineered Using the Sleeping Beauty Transposon/Transposase System to Express T-Cell Receptors Reactive Against Mutated Neoantigens in Patients With Metastatic Cancer (NCT0402436). Under the direction of Steven Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI, and his team, the trial will enroll patients with a range of solid cancers.

- **New agreement with MD Anderson Cancer Center accelerates TCR hotspot library expansion and enables future Ziopharm clinical trials:** Ziopharm announced last week a new research and development agreement with MD Anderson for the *Sleeping Beauty* immunotherapy program to use non-viral gene transfer to stably express and clinically evaluate neoantigen-specific TCRs in T cells. This agreement will accelerate expansion of the library of TCRs against neoantigens in hotspots including mutated KRAS, TP53 and EGFR licensed from NCI earlier this year. Additionally, this agreement provides the foundation for two new Ziopharm TCR-T clinical trials to be conducted at MD Anderson: a trial for utilizing TCRs from the library targeting hotspot mutations, and a second trial for personalized TCRs targeting patient-specific neoantigens.

Sleeping Beauty CAR-T

Ziopharm is advancing the *Sleeping Beauty* platform for the rapid personalized manufacture (RPM) of CD19-specific CAR-T, co-expressing membrane bound IL-15 (mbIL15) with a safety switch. Per the IND, RPM produces T cells with viability of at least 70% that can be infused the day after gene transfer. 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.

- **FDA Cleared IND for phase 1 trial for RPM of CD19-specific CAR-T:** In October, the Company announced that FDA cleared an IND for a phase 1 clinical trial to assess CD19-specific CAR-T, produced using RPM. The study will be conducted at MD Anderson as an investigator-initiated trial. Patients with $CD19^+$ leukemias and lymphomas who have relapsed after allogeneic bone marrow transplantation will be enrolled to evaluate infusion of donor-derived RPM CAR-T.

- **Abstract accepted at 2019 ASH Annual Meeting: Investigators** will present preclinical data on the benefit of mbIL15 on the rapid personalized manufacture (RPM) of TCR-T at the 2019 Annual Meeting of the American Society of Hematology in December.

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 monotherapy and in combination with immune checkpoint inhibitors. In August, supportive data from the phase 1 monotherapy trial were published in *Science Translational Medicine*.

- **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). Investigators from this multi-center trial indicated interest in expanding the study and have enrolled all 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 at the end of the second quarter to evaluate Ad-RTS-hIL-12 plus veledimex in combination with Regeneron's PD-1 antibody Libtayo to treat patients with rGBM. As prescribed in the study protocol, the first six patients have been dosed, and are completing the required monitoring period prior to the resumption of enrollment. The Company expects to enroll about 30 patients at approximately 10 sites.

- **Abstracts accepted at 2019 SNO Annual Meeting:** Investigators will present data from two ongoing trials in the Controlled IL-12 platform, both as monotherapy and in combination with OPDIVO, in two posters at the 2019 Annual Meeting of the Society for Neuro-Oncology (SNO) in November.

- **EMA grants Orphan Drug status to Controlled IL-12 program:** Ziopharm announced in August that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) adopted a positive opinion recommending Controlled IL-12 for designation as an orphan medicinal product for the treatment of glioma, which has subsequently been adopted by the European Commission.

Corporate Updates

- **Balance sheet strengthened: Early in the third quarter,** 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 $52 million. With more than $88 million in cash at the end of the third quarter, Ziopharm has sufficient capital to fund operations into the first half of 2021 and provide visibility into important clinical data milestones for the Company's TCR-T, CAR-T and Controlled IL-12 programs.

- **Expanded Ziopharm Laboratory and Office on MD Anderson Campus:** Concurrent with the new R&D agreement with MD Anderson announced last week, through a new lease Ziopharm is also significantly expanding its R&D footprint on the MD Anderson campus.

- **Dr. Chris Bowden joins Board of Directors:** In October, Ziopharm appointed Chris Bowden, M.D., an oncology drug development executive with more than 20 years leadership experience spanning pre-clinical development through commercialization, including the approval of several cancer medicines, to the Company's Board. The addition of Dr. Bowden represents the sixth new board member for Ziopharm in the past 18 months.

Third Quarter 2019 Financial Results

- The Company recorded a one-time, non-cash charge during the quarter of $60.8 million associated with the warrant exercise transaction.
- Reflecting the $60.8 million, ($0.36) per share, non-cash charge, the net loss applicable to the common shareholders for the third quarter of 2019 was $74.0 million, or $(0.43) per share, compared to a net loss of $18.7 million, or $(0.13) per share, for the third quarter of 2018.
- Research and development expenses were $8.6 million for the third quarter of 2019, compared to $8.3 million for the third quarter of 2018.
- General and administrative expenses were $4.8 million for the third quarter of 2019, compared to $4.3 million for the third quarter of 2018.
- The Company ended the quarter with unrestricted cash resources of approximately $88 million.
- In addition, a prepayment of approximately $21.5 million remains for programs to be conducted by the Company at MD

Anderson under the current Research and Development Agreement.

– Financial Tables Follow –

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

	Three Months Ended September 30, (unaudited)	
	2019	**2018**
Collaboration revenue	$ -	$ -
Operating expenses:		
Research and development	8,641	8,263
General and administrative	4,807	4,307
Total operating expenses	13,448	12,570
Loss from operations	(13,448)	(12,570)
Other income, net	203	150
Change in fair value of derivative liabilities	-	(165)
Noncash inducement warrant expense	(60,751)	-
Net loss	(73,996)	(12,585)
Preferred stock dividends	-	(6,074)
Net Income (loss) applicable to common stockholders	$ (73,996)	$ (18,659)
Basic and diluted net loss per share	$ (0.43)	$ (0.13)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	170,613,712	141,185,404

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

	September 30, 2019	**December 31, 2018**
Cash and cash equivalents	88,419	61,729
Working capital	104,423	74,802
Total assets	117,949	95,051
Total stockholders' equity	106,126	85,564

Conference Call and Webcast
Scheduled for today at 4:30 pm ET, the conference 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 8286838. 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 neoantigens inside and outside hotspots for solid tumors and CAR to target CD19 for blood cancers using the Company's RPM to produce and release CAR-T as soon as the day after gene transfer. 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 is also 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.

Ziopharm Contacts:
Chris Taylor
VP, Investor Relations and Corporate Communications
T: 617.502.1881
E: ctaylor@ziopharm.com

Lisa M. Wilson
In-Site Communications, Inc.
E: lwilson@insitecony.com

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