Ziopharm Oncology Reports Financial Results for Fourth Quarter and Full Year 2019

March 2, 2020

– Emergence of TCR program, Controlled IL-12 data, strengthened team highlight 2019 –

– Balance sheet strengthened; cash of approximately $177 million funds operations to mid-2022 –

– Clinical trial milestones and data readouts in 1H20 –

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

BOSTON, March 02, 2020 (GLOBE NEWSWIRE) -- Ziopharm Oncology, Inc. ("Ziopharm" or the "Company") (Nasdaq: ZIOP), today announced its financial results for the fourth quarter and year ended December 31, 2019 and provided a corporate update.

"In the 16 months since forging our corporate independence, we have advanced all our clinical programs, licensed critical intellectual property, recruited key personnel to the Company and Board, and fortified our financial position," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer. "In 2020, we will use this foundation to accelerate our commercial pathway, through enrollment at NCI to TCR-T trial, preparing TCR-T trials with MD Anderson Cancer Center, data readouts on Controlled IL-12 in recurrent GBM and enrollment to trial of CAR-T infused day after gene transfer."

Significant 2019 Achievements

- **NCI Phase 2 TCR Study.** Under the T-cell receptor (TCR) T-cell therapy program, an investigational new drug (IND) application submitted by the National Cancer Institute (NCI) received clearance from the U.S. Food and Drug Administration (FDA) for a phase 2 clinical trial in multiple solid tumors to evaluate use of the *Sleeping Beauty* platform for TCR-T therapy.
  - This trial represents a first-in-human non-viral TCR-T trial at NCI.
  - NCI has begun to screen patients for enrollment with patients going through the TCR identification and procurement process; with tumor resection, neoantigen identification, and TCRs made ready for infusion.
  - Study protocol details are available on Clinicaltrials.gov: 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).

- **New MD Anderson Agreement**. In October, the Company entered into a lease agreement to expand its R&D footprint and entered into a new Research and Development Agreement with MD Anderson Cancer Center which:
  - Enables Ziopharm-sponsored clinical studies at MD Anderson based on the *Sleeping Beauty* non-viral gene transfer platform to generate T cells targeting neoantigens in solid tumors; initially, two approaches will be evaluated infusing autologous T cells expressing TCRs with specificities for multiple private neoantigens and administering autologous T cells expressing TCRs from a library targeting shared neoantigens in hotspots.
  - Accelerates expansion of the library, licensed from NCI earlier in 2019, of TCRs against neoantigens in hotspots including mutated KRAS, TP53 and EGFR.

- **Phase 2 Combination Study for Controlled IL-12.** Under the Controlled IL-12 program, the Company initiated a phase 2 combination trial with Regeneron's Libtayo ® to treat patients with recurrent glioblastoma (rGBM).
  - As prescribed in the study protocol, the Company expects to enroll up to 36 patients at approximately 10 sites. Enrollment is anticipated to be completed in 1H 2020.
  - This phase 2 trial builds on experience from a phase 1 combination study with another PD-1 inhibitor, OPDIVO®, which completed enrollment last year, with additional data expected this year.

- **Controlled IL-12 Clinical Data.** Data publications in 2019 at the American Society of Clinical Oncology (ASCO) and Society for Neuro-Oncology (SNO) annual meetings showed Controlled IL-12, as monotherapy or in combination with a PD-1 inhibitor, resulted in immune-mediated anti-tumor effects in the setting of recurrent GBM. Encouraging results from the phase 1 monotherapy main trial were published in *Science Translational Medicine.* These publications and

presentations are available on Ziopharm's website.

- **IND Cleared for CAR-T Study.** Under the CAR-T program, an IND was cleared by the FDA for a phase 1 clinical trial to assess CD19-specific CAR-T, produced using Rapid Personalized Manufacturing (RPM).
    - Up to 24 patients will be enrolled to evaluate infusion of donor-derived RPM CAR-T in patients with $CD19^+$ leukemias and lymphomas who have relapsed after allogeneic bone marrow transplant. This study is being conducted at MD Anderson Cancer Center as an investigator-initiated trial.
    - The Company also expects partners at Eden BioCell to file an IND for an autologous RPM CD19 trial this year in Taiwan.

- **Expanded Team and Capabilities.** The Company experienced significant growth in 2019, with strategic hires expanding capabilities and increasing staff nearly 50 percent to 73 employees at year end.
    - Notably, Ziopharm welcomed Sath Shukla, formerly of Vertex Pharmaceuticals, as Chief Financial Officer and Dr. Drew Deniger, who previously worked under Dr. Steven Rosenberg at the NCI, to lead the TCR program.
    - Chris Bowden, M.D., and Heidi Hagen were appointed as Directors, completing the repopulation of the Board as part of Ziopharm's reemergence as an independent company.

- **Strengthened Balance Sheet.** Ziopharm completed 2019 with approximately $79.7 million in cash, with another $20.3 million in capital pre-funded at MD Anderson available for the Company's program.
    - Subsequent to the close of 2019, the Company raised approximately an additional $98 million through recent financing activities, Ziopharm has dramatically extended its funding horizon and can accelerate the buildout of its TCR program in Houston and the launch of Ziopharm-led TCR clinical trials for patients with solid tumors.

Anticipated Milestones for the First Half of 2020

- ***Sleeping Beauty* Cell Therapy Programs**
    - Patient dosing in the NCI-led phase 2 TCR-T trial targeting solid tumors.
    - Initiation of the CD19-specific CAR-T RPM phase 1 trial with membrane bound IL-15 at MD Anderson.

- **Controlled IL-12 Gene Therapy Program**
    - Complete enrollment and initial data readout for phase 2 combination trial with Libtayo®.
    - Interim data readout of phase 1 combination trial with OPDIVO®.
    - Interim data readout from phase 1 monotherapy trial in expanded cohort.

Fourth Quarter 2019 Financial Results

- Net loss of the fourth quarter of 2019, was $15.7 million, or $(0.09) per share, compared to net income of $194.5 million, or $1.29 per share, for the fourth quarter of 2018. Net income for the fourth quarter of 2018 reflects the forfeiture and return of all the Company's Series 1 preferred stock held by a former corporate partner and the relinquishment of Ziopharm's obligations under a separate agreement, accounting for approximately $207 million.
- Research and development expenses were $10.2 million for the fourth quarter of 2019, compared to $8.2 million for the fourth quarter of 2018, primarily reflecting increased clinical trial activity.
- General and administrative expenses were $5.8 million for the fourth quarter of 2019, compared to $4.6 million for the fourth quarter of 2018. The increase in general and administrative expenses for the fourth quarter of 2019 is primarily due to increased headcount, growth of intellectual property activity and expanded clinical activity.
- The Company ended the fourth quarter 2019 with unrestricted cash resources of approximately $79.7 million.
- In addition, a prepayment of approximately $20.3 million remains for work to be conducted by the Company at MD Anderson under the Company's Research and Development Agreements.

Full Year 2019 Financial Results

- Net loss applicable to the common shareholders for the year ended December 31, 2019 was $117.8 million, or $(0.70) per share, basic and diluted, compared to net income applicable to the common shareholders of $137.2 million, or $0.96 per share, basic and diluted, for the year ended December 31, 2018. Net income in 2018 reflects the forfeiture and return of all of the Company's Series 1 preferred stock held by a former corporate partner and the relinquishment of Ziopharm's obligations under a separate agreement, accounting for approximately $207 million.
- Research and development expenses were $38.3 million for the year ended December 31, 2019, compared to $34.1 million for the year ended December 31, 2018. The increase in research and development expenses for the year ended December 31, 2019 is primarily due to expanded clinical trial activity.
- General and administrative expenses were $19.5 million for the year ended December 31, 2019, compared to $19.9 million for the year ended December 31, 2018.

Conference Call and Webcast
Scheduled for today at 4:30 p.m. 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 6773016. 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 T-cell receptor (TCR) and chimeric antigen receptor (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 "Rapid Personalized Manufacturing" 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 Annual Report on Form 10-K 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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– Financial Tables Follow –

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

	Three Months Ended December 31, (unaudited)		Year Ended December 31, (audited)	
	2019	**2018**	**2019**	**2018**
Collaboration revenue	$ -	$ -	$ -	$ 146
Operating expenses:				
Research and development	10,216	8,199	38,331	34,134
General and administrative	5,820	4,563	19,527	19,918
Total operating expenses	16,036	12,762	57,858	54,052
Loss from operations	(16,036)	(12,762)	(57,858)	(53,906)
Other income (expense), net	290	168	813	631
Change in fair value of derivative liabilities	-	113	-	158
Noncash inducement warrant expense	-	-	(60,751)	-
Net loss	(15,746)	(12,481)	(117,796)	(53,117)
Preferred stock dividends	-	(342)	-	(16,998)
Settlement of a related party relationship	-	207,361	-	207,361

Net Income (loss) applicable to common stockholders	$ (15,746)	$ 194,538	$ (117,796)	$ 137,246
Net income (loss) per share - basic	$ (0.09)	$ 1.29	$ (0.70)	$ 0.96
Net income (loss) per share - diluted	$ (0.09)	$ 1.29	$ (0.70)	$ 0.96
Weighted average common shares outstanding used to compute basic net income (loss) per share	179,522,225	150,893,470	167,952,114	143,508,674
Weighted average common shares outstanding used to compute diluted net income (loss) per share	179,522,225	151,094,956	167,952,114	143,710,160

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

	December 31, 2019	2018
Cash and cash equivalents	79,741	61,729
Working capital	92,966	74,802
Total assets	109,114	95,051
Total stockholders' equity	95,010	85,564

Source: ZIOPHARM Oncology Inc