# Ziopharm Oncology Provides Second Quarter 2021 Corporate Updates

August 9, 2021

*Accomplished key milestones in groundbreaking TCR-T Library program, including commissioning of Company's manufacturing facility and presentation of favorable preclinical data*

*Closed venture debt financing with Silicon Valley Bank, strengthening balance sheet and extending cash runway into the fourth quarter of 2022*

*Provided update on CD19 RPM CAR-T trial being conducted by Eden BioCell*

*Conference call scheduled for today at 4:30 pm EDT*

BOSTON, Aug. 09, 2021 (GLOBE NEWSWIRE) -- Ziopharm Oncology, Inc. ("Ziopharm" or the "Company") (Nasdaq: ZIOP), today provided corporate updates for the second quarter of 2021, ended June 30, 2021. The Company will host a conference call and webcast today at 4:30 pm EDT.

"Since our last update, the Company has made tremendous progress across multiple fronts," said Heidi Hagen, Interim Chief Executive Officer. "The Company has built significant positive momentum in our TCR-T Library clinical trial enabling activities and in our efforts to strengthen the balance sheet. This quarterly update reflects the Company doing exactly what we said we would do earlier in the year and this is very exciting to see. The appointment of a permanent CEO is also something we look forward to in the very near future. The strong science underlying our work continues to provide us with confidence as we move forward. On behalf of the Board and management team, I want to thank all our dedicated researchers, scientists, partners, and the entire organization for their commitment to our mission."

**Significant Progress in Company's TCR-T Library Clinical Program**

Since the last quarterly update, the Company achieved several key milestones in its TCR-T Program. Importantly, the Company remains on track to begin dosing patients in its Phase I/II TCR-T Library trial during the second half of 2021, and now anticipates dosing the first patient during the fourth quarter of this year. The trial initially targets six individual solid tumor indications: cholangiocarcinoma, pancreatic cancer, ovarian cancer, endometrial cancer, colorectal cancer, and lung cancer, which were selected due to the frequency of KRAS and / or TP53 mutations. The Company intends on expanding into additional indications in the future.

The clinical trial will open for enrollment upon establishing clinical manufacturing readiness. During 2020, the Company successfully transferred the manufacturing process for its TCR-T cell products to KBI Biopharma, a previously undisclosed contract manufacturing organization with cGMP cell therapy manufacturing facilities in The Woodlands, TX. TCR-T batch data generated at both KBI and the Company's own laboratory were the basis of the Chemistry, Manufacturing and Controls portion of the Investigational New Drug Application (IND) filed earlier this year. KBI is now working to complete the process qualification and aseptic process validation to facilitate clinical manufacturing.

Additionally, the Company has been implementing a strategy to build in-house cGMP clinical production capabilities at the Company's facility in Houston, TX. This is being done to provide greater flexibility and control of this important aspect of clinical development and the Company is moving forward rapidly to establish these manufacturing capabilities. The commissioning of the Company's clinical production unit (CPU), as well as aseptic process validation, were completed this past quarter, which are meaningful steps in establishing the CPU's capabilities. The team is completing process qualification, which will support the opening of the facility to manufacture TCR-T cells for the clinical trial. The ability to use both its in-house facility and KBI's facility for manufacturing will provide the Company a strong degree of risk mitigation and greater capacity as the Company scales up clinical trial activities.

The Company continues to qualify TCRs in its Library and plans to amend the IND during the second half of 2021 to include these additional TCRs. The Company expects that the supplemental TCRs will expand the potential utility, applicable patient population, and addressable commercial market for the Library, and may include additional KRAS and / or TP53 mutations or other genetic hotspots associated with solid tumors such as EGFR.

During the second quarter, the Company presented a poster at the annual American Association of Cancer Research (AACR) meeting, entitled "Hotspot mutations in KRAS targeted by TCR-T cells genetically modified with the *Sleeping Beauty* transposon/transposase system". The poster highlighted preclinical work regarding the Company's TCR-T program and demonstrated that multiple TCRs with unique specificities targeting recurrent p53 and KRAS substitutions in frequent HLA haplotypes could be stably expressed using *Sleeping Beauty* transposition to re-direct peripheral blood T-cells towards tumor cells. The Company plans on providing additional preclinical data further demonstrating the strong science behind the program later this year at a scientific conference.

"Our TCR-T program continues to build momentum scientifically and clinically, and we remain poised to begin dosing during the fourth quarter of this year. We have begun pre-screening patients and based on initial data from investigators, we are very optimistic that we will consistently find mutation / HLA combinations within the targeted patient populations that match TCRs in our Library," said Raffaele Baffa, MD, Ph.D., Chief Medical Officer. "I thank the team for their tremendous efforts as they work to ensure success."

**Closing of Venture Debt Financing with Silicon Valley Bank**

The Company today announced that it has closed a venture debt facility with Silicon Valley Bank in the aggregate amount of $50 million. The Company will draw down an initial $25 million tranche from this facility immediately. A second $25 million tranche is available contingent on the achievement of certain clinical milestones and other conditions.

The initial $25 million tranche extends the Company's cash runway into the fourth quarter of 2022, well beyond the time required to generate and assess the initial clinical data from the Company's Phase I/II TCR-T Library trial.

Holger Weis, member of the Board of Directors and Chair of the Audit Committee, commented, "We have developed a very strong relationship with Silicon Valley Bank and are happy to have its partnership and support on this funding. This debt vehicle will be used in a prudent and judicious manner and extends the Company's cash runway significantly. This is a clear demonstration that the Company is being guided by strong consideration of shareholder impact and a desire to support expanding shareholder value through our capital strategy and tactics."

**Update on Phase I CD19 RPM CAR-T Trial Being Conducted by Eden BioCell in Taiwan**

As previously disclosed, in March 2021, Eden BioCell, the Company's Joint Venture in Taiwan with TriArm Therapeutics, began treating patients in a clinical trial with the Company's investigational CD19 RPM CAR-T cell therapy, under the Phase I IND cleared by the Taiwan Food and Drug Administration in December 2020. The Company today provided an update on this program.

Two patients have been treated in the trial. The lead investigator at National Taiwan University in Taipei has reported no serious adverse safety events in either of these patients. Laboratory results continue to support, as previously published, that non-viral *Sleeping Beauty* gene transfer is effective in genetically modifying autologous T-cells. Patients were infused two days after gene transfer, thus shortening the turnaround time and providing a clear advantage over viral methods.

However, based on laboratory data generated from the first two patients between March and May 2021, the TriArm/Eden BioCell team concluded, in concert with the lead investigator and with the support from the team at Ziopharm, that further process development work is required. This additional work is intended to optimize and refine the manufacturing process in order to manufacture cells more consistently in the desired clinical dose range seeking to be studied.

Per the terms of the Joint Venture agreement, the TriArm/Eden BioCell team will work towards the necessary process development improvements before infusing additional patients. The length of time to do so is unknown and maybe require up to 12 months. The ongoing COVID-19 outbreak in Taiwan presents added uncertainty, as the operational activities in the manufacturing facility are currently limited due to employee restrictions related to the pandemic. These restrictions are impacting clinical trials broadly in Taiwan.

Additionally, consistent with its strategic focus on TCR, the Company is seeking and considering broader partnerships to enable further development of the investigational CD19 RPM CAR-T cell therapy. Several parties have expressed interest in such a partnership, including TriArm Therapeutics. The Company will carefully consider all options regarding the future of the Joint Venture, the technology, and the global development pathway, in order to maximize shareholder value.

The Company noted the distinctions between the CAR-T program and the TCR-T program. "As we have previously described, the TCR and CAR-T processes are intrinsically different and follow very separate process development pathways," commented Dr. Baffa. "While both involve *Sleeping Beauty* gene transfer, the constructs, and manufacturing processes are very distinct. The unique clinical presentations and challenges associated with the treatment of blood cancers and solid tumors also reflect differences and we believe the recent findings from CAR-T do not read through to the TCR-T program."

**Update on Search for Permanent Chief Executive Officer**

The Company expects to make an announcement regarding its permanent CEO position in the near future.

Robert Postma, member of the Board of Directors, said, "We have seen and considered a number of very strong and qualified candidates during the search, and the Board is in the final stages of selecting our new CEO."

**Cash Position**

- As of June 30, 2021, the Company had approximately $76.7 million of cash and cash equivalents. This amount is unaudited and preliminary, and does not present all information necessary for an understanding of our financial condition as of June 30, 2021, which will be presented in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021.

- Additionally, a prepayment of approximately $1.8 million remains for work to be conducted by the Company at MD Anderson under the Company's research and development agreements.

- The $25 million drawdown of the Silicon Valley Bank debt facility is not included in the above figure as it was closed subsequent to June 30, 2021.

**Conference Call and Webcast**

Ziopharm will host a conference call and webcast for the investment community today, August 9, 2021, at 4:30 p.m. EDT. The conference call can be accessed by dialing 877-451-6152 (U.S. and Canada) or 201-389-0879 (International). The passcode for the conference call is 13721210. A live webcast may be accessed using the link here, or by visiting the "Investors" section of the Ziopharm website at www.ziopharm.com. The call will be recorded and available for replay on the Company's website for approximately 90 days after the call.

**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 cancer each year. With its multiplatform approach, Ziopharm is at the forefront of immuno-oncology. Ziopharm's pipeline is built for commercially scalable, cost-effective T-cell receptor (TCR) T-cell therapies based on its non-viral *Sleeping Beauty* gene transfer platform, a rapidly manufactured *Sleeping Beauty*-enabled CD19-specific CAR-T program and a precisely controlled IL-12 gene therapy. The Company has clinical and strategic collaborations with the National Cancer Institute and The University of Texas MD Anderson Cancer Center. 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 Company's business and strategic plans, the wind down of the Company's Controlled IL-12 clinical program, the timing of activities relating to the Company's GMP facility, the execution of potential future partnerships or transactions, and the timing of the Company's research and development programs, including the anticipated dates for enrolling patients in the Company's TCR-T clinical trial. 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 the Company's operating plans that may impact its 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 in the most recent Form 10-Q and 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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