UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): June 27, 2019

ZIOPHARM Oncology, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-33038	84-1475642
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One First Avenue, Parris Building 34, Navy Yard Plaza Boston, Massachusetts	02129
(Address of Principal Executive Offices)	(Zip Code)

(617) 259-1970
(Registrant's telephone number, including area code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ZIOP**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act (17 CFR 230.405) or Rule 12b-2 of the Exchange Act (17 CFR 240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 27, 2019, Ziopharm Oncology, Inc. issued a press release announcing the initiation of a Phase 2 clinical trial evaluating Controlled IL-12 (Ad-RTS-hIL-12 plus veledimex) in combination with PD-1 antibody Libtayo® (cemiplimab-rwlc) for the treatment of recurrent or progressive glioblastoma multiforme in adults.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 27, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ZIOPHARM ONCOLOGY, INC.

By: /s/ Robert Hadfield
Name: Robert Hadfield
Title: General Counsel and Secretary

Date: June 27, 2019

Exhibit 99.1

Ziopharm Oncology Initiates Phase 2 Trial Evaluating Combination Therapy of Controlled IL-12 with Libtayo® (cemiplimab-rwlc) to Treat Patients with Recurrent Glioblastoma

– Phase 2 trial will enroll approximately 30 patients and evaluate both safety and efficacy –

BOSTON, June 27, 2019 — Ziopharm Oncology, Inc. ("Ziopharm" or "the Company") (Nasdaq:ZIOP) today announced the initiation of a phase 2 clinical trial evaluating Controlled IL-12 (Ad-RTS-hIL-12 plus veledimex, Ad+V), in combination with PD-1 antibody Libtayo® (cemiplimab-rwlc) for the treatment of recurrent or progressive glioblastoma multiforme (rGBM) in adults. The multi-center trial will be conducted at approximately 10 hospitals specializing in the treatment of brain cancers in the United States.

"We piloted the combination of interleukin-12 (IL-12) and a PD-1-specific antibody in a phase 1 trial which lays the foundation for recruitment to this phase 2 study for patients with rGBM. This trial seeks to further IL-12, which activates the patient's own immune system to attack cancer, by coupling with the inhibition of PD-1 to enhance the effectiveness of the combination," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm.

Ziopharm's Controlled IL-12 platform is an investigational gene therapy designed to induce and control the production of human interleukin 12 (hIL-12) a master-regulator of the immune system. In the setting of rGBM, the Company is leveraging the anti-tumor effects for Controlled IL-12 as monotherapy by combining with PD-1 inhibitors. Previously reported data from serial biopsies in patients with rGBM revealed that Controlled IL-12 results in sustained influx of T cells and upregulation of PD-1 expression, providing a compelling rationale for this combination. Initial phase 1 data from this trial were presented at the American Society for Clinical Oncology (ASCO) on June 2, 2019, showing Controlled IL-12 can be combined with PD-1 inhibitor nivolumab and the initial data were consistent with immune mediated anti-tumor effects with a favorable safety profile.

The open-label, single-arm phase 2 trial will enroll approximately 30 patients with rGBM, with the primary endpoints being safety and efficacy. Patients with rGBM scheduled for resection who have not been treated previously with inhibitors of immune-checkpoint pathways will receive Ad-RTS-hIL-12 intratumorally at the time of surgical resection plus a dose of veledimex (20mg), an oral activator ligand, daily for 14 days. Patients will receive cemiplimab intravenously (350 mg) every three weeks until documented progression or withdrawal from the study.

Regeneron, in collaboration with Sanofi, is developing cemiplimab both alone and in combination with other therapies for the treatment of various cancers. In November 2018, Ziopharm and Regeneron entered a clinical supply agreement to evaluate combination therapy of Ziopharm's Controlled IL-12 with Regeneron's PD-1 antibody cemiplimab to treat patients with rGBM.

Additional information about the study will be available at https://clinicaltrials.gov.

About Ad-RTS-hIL-12 plus veledimex

The Company has treated more than 100 patients, including more than 75 patients with rGBM, with Ad-RTS-hIL-12 plus veledimex and administered more than 1,300 doses of veledimex across three types of solid tumors, building a significant safety profile, mechanistic dataset and evidence of anti-tumor effects.

At the 2018 annual meeting of the Society for Neuro-Oncology, Ziopharm presented data from its phase 1 dose-escalation trial showing that Controlled IL-12 had a positive survival benefit, with 15 patients who received 20mg veledimex reaching 12.7 months median overall survival (mOS) at a mean follow up of 13.1 months. A subset of these patients (n=6) who received low-dose steroids (20mg or less of dexamethasone cumulatively over 15 days while receiving veledimex) had mOS of 17.8 months compared to 6.4 months mOS for patients (n=9) who received more than 20mg of dexamethasone during the same period. The survival data from patients who received the preferred dosing regimen of Controlled IL-12 with 20mg veledimex and low-dose steroids compare favorably to a benchmark mOS of 6 to 9 months for patients with rGBM that serves as historical control.

In February, the Company announced that it rapidly completed enrollment and treated 36 additional patients at 20mg veledimex dosing in less than six months in a substudy (Clinicaltrials.gov NCT03679754) to expand a phase 1 trial evaluating its Controlled IL-12 platform as a monotherapy for the treatment of rGBM. A majority (75%) of patients enrolled in the substudy were treated with low-dose steroids. At ASCO 2019, the Company presented data which confirmed that local, regulated IL-12 production using Ad+V in subjects with rGBM rapidly and safely activates the immune system, with adverse reactions consistent and predictable to those seen in prior studies, and promptly reversible upon discontinuation of veledimex. Mean follow-up was 3.7 months.

About Ad-RTS-hIL-12 plus veledimex in combination with PD-1 inhibitors

In a separate phase 1 trial to evaluate Controlled IL-12 in combination with the PD-1 inhibitor nivolumab, (Clinicaltrials.gov NCT03636477), the Company reported initial data and observations at the 2019 ASCO Annual Meeting earlier this month. With a mean follow-up of 4.5 months, the Cytoindex (an emerging biomarker) improved compared with Ad+V as monotherapy lending support that the combination may lead to improved overall survival. Data from three dosing cohorts evaluated increasing doses of veledimex and PD-1 inhibitor revealed a similar safety profile as Ad+V monotherapy. Adverse reactions from all cohorts were manageable and reversible without synergistic toxicities, while adverse reactions during follow-on nivolumab dosing were consistent with reports for PD-1 inhibition. Seven of the 9 patients in the study received low-dose steroids. The Company has completed dose escalation and anticipates enrolling additional patients with rGBM (to receive 20 mg of veledimex and 3 mg/kg of nivolumab).

FDA Fast Track Designation

In April 2019, Ziopharm announced that FDA had granted Fast Track designation for the Company's Controlled IL-12 program for the treatment of rGBM in adults. The Fast Track program is designed to facilitate the expedited development and review of drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

Learn more about Controlled IL-12 online at https://ziopharm.com/controlled-il-12/.

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.

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 Controlled IL-12 program in treating patients with rGBM and the progress and timing of the development of Ziopharm'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 clearance from the U.S. Food and Drug Administration (FDA) or equivalent foreign regulatory agencies to conduct clinical trials and whether and when, if at all, they will receive final approval from the 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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