# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

	DIA	Ω	T
ΗU	RM	Ø-	·N

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

Date of report (Date of earliest event reported): July 19, 2016

## ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

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

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

02129 (Zip Code)

(617) 259-1970 (Registrant's Telephone Number, including Area Code)

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

ck 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 isions:
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)).

#### Item 7.01 Regulation FD Disclosure

On July 19, 2016, ZIOPHARM Oncology, Inc., or the Company, issued a press release providing an update regarding the Company's ongoing multicenter Phase 1 study of Ad-RTS-hIL-12 + orally administered veledimex in recurrent or progressive glioblastoma (GBM) or grade III malignant glioma.

The information contained in the Press Release furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any of the Company's filings, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

#### Item 9.01 <u>Financial Statements and Exhibits</u>

(d) Exhibits

Exhibit No. Description

99.1 Press Release of the Company dated July 19, 2016

#### **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/ Kevin G. Lafond

Name: Kevin G. Lafond

Title: Vice President, Chief Accounting Officer and Treasurer

Date: July 19, 2016

#### INDEX OF EXHIBITS

Exhibit No. Description

99.1 Press Release of the Company dated July 19, 2016

4



### ZIOPHARM Oncology, Inc.

ZIOPHARM Provides Update Regarding Phase I Study of Gene Therapy Candidate Ad-RTS-hIL-12 in Brain Cancer

**BOSTON, MA – July 19, 2016** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today provided an update regarding the Company's ongoing multicenter Phase 1 study of Ad-RTS-hIL-12 + orally administered veledimex in recurrent or progressive glioblastoma (GBM) or grade III malignant glioma.

The patient death resulting from intracranial hemorrhage in the third cohort of this Phase I study was deemed unrelated to study drug following the receipt and analysis of additional information by the sponsor and the study's Safety Review Committee. As with all study events, the Company expects to report the data to the U.S. Food and Drug Administration in accordance with the study's protocol and applicable regulations. As previously announced, the study remains open for enrollment. The Company expects to provide further updates on the progress of the study, including longer-term survival follow up, at an appropriate meeting later this year.

"Recurrent GBM is a devastating disease with an expected overall survival that remains far too short as this case illustrates," said Francois Lebel, M.D., Executive Vice President, Research and Development, Chief Medical Officer at ZIOPHARM. "Preliminary overall survival in this study, including a median follow-up of over 8 months in the first dose cohort, remain encouraging, and we will continue to work diligently toward understanding the full potential of Ad-RTS-hIL-12 + veledimex in this disease, with the goal of providing safe and effective treatment options to these patients."

#### **About Glioblastoma**

Glioblastoma is an aggressive primary brain tumor affecting approximately 74,000 people worldwide each year.<sup>i, ii</sup> Recurrent glioblastoma is an aggressive cancer with one of the lowest 3-year survival rates, at 3%, among all cancers.<sup>iii</sup> For patients who have experienced multiple recurrences the prognosis is particularly poor, with a median overall survival (OS) of 6-7 months, while OS in patients that have failed temozolomide and bevacizumab, or equivalent salvage chemotherapy, is approximately 3-5 months.<sup>iv, v</sup>

#### About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a Boston, Massachusetts-based biotechnology company employing novel gene expression, control and cell technologies to deliver safe, effective and scalable cell- and viral-based therapies for the treatment of cancer. The Company's immuno-oncology programs, in collaboration with Intrexon Corporation (NYSE:XON) and the MD Anderson Cancer Center, include chimeric antigen receptor T cell (CAR-T) and other adoptive cell-based approaches that use non-viral gene transfer methods for broad scalability. The Company is advancing programs in multiple stages of development together with Intrexon Corporation's RheoSwitch Therapeutic System® technology, a switch to turn on and off, and precisely

modulate, gene expression in order to improve therapeutic index. The Company's pipeline includes a number of cell-based therapeutics in both clinical and preclinical testing which are focused on hematologic and solid tumor malignancies.

#### Forward-Looking Safe-Harbor Statement:

This press release contains certain forward-looking information about ZIOPHARM Oncology. Inc. that is intended to be covered by the safe harbor for "forward-looking statements" provided by 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 progress, timing and results of preclinical and clinical trials involving the Company's drug candidates, and the progress of the Company's research and development programs. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied by, the forward-looking statements. These risks and uncertainties include, but are not limited to: whether chimeric antigen receptor T cell (CAR T) approaches, Ad-RTS-hIL-12, TCR and NK cell-based therapies, or any of our other therapeutic candidates will advance further in the pre-clinical or clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether chimeric antigen receptor T cell (CAR T) approaches, Ad-RTS-hIL-12, TCR and NK cell-based therapies, and our other therapeutic products will be successfully marketed if approved; the strength and enforceability of our intellectual property rights; competition from other pharmaceutical and biotechnology companies; and the other risk factors contained in our periodic and interim SEC reports filed from time to time with the Securities and Exchange Commission, including but not limited to, our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and our Quarterly Report for the quarter ended March 31, 2016. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

#### **Trademarks:**

RheoSwitch Therapeutic System® (RTS®) technology is a registered trademark of Intrexon Corporation.

- Mrugala MM. Advances and challenges in the treatment of glioblastoma: a clinician's perspective. Discov Med. 2013;15:221-230. http://www.discoverymedicine.com/Maciej-M-Mrugala/2013/04/25/advances-and-challenges-in-the-treatment-of-glioblastoma-a-clinicians-perspective/. Accessed March 24, 2015.
- ii. McCubrey JA, LaHair MM, Franklin RA. OSU—0312 in the treatment of glioblastoma. Mol Pharmacol. 2006;70:437-439.
- iii. International Agency for Research on Cancer. World Cancer Report. 2003. <a href="http://www.iarc.fr/en/publications/pdfs-online/wcr/2003/WorldCancerReport.pdf">http://www.iarc.fr/en/publications/pdfs-online/wcr/2003/WorldCancerReport.pdf</a>.
- iv. Omuro, A. Glioblastoma and Other Malignant Gliomas. A Clinical Review JAMA. 2013 Nov 6;310(17):1842-50.
- v. Iwamoto et al. Patterns or relapse and prognosis after bevacizumab failure in recurrent glioblastoma. Neurology 2009; 73(15):1200-1206

Contact: Lori Ann Occhiogrosso ZIOPHARM Oncology, Inc. 617-259-1987 locchiogrosso@ziopharm.com

David Pitts Argot Partners 212-600-1902 david@argotpartners.com