Ziopharm Oncology Responds to Recent Stock Decline and Clarifies Exclusivity Rights for Clinical Assets

December 27, 2018

BOSTON, Dec. 27, 2018 (GLOBE NEWSWIRE) -- Ziopharm Oncology, Inc. (Nasdaq:ZIOP) today responded to the recent decline in the Company's stock price, which accelerated greatly on December 26, 2018, the same day that the broader market and all indexes were up significantly. To the extent this price drop may have been attributable to any market confusion over exclusivity to its assets, the Company wishes to make clear the terms of its exclusivity to such assets.

"Our stock price is significantly down of late, and we want to assure the market that our business fundamentals are unchanged and we are optimistic about Ziopharm's future especially in light of the recent announcements we made with regards to our restructured relationship with Intrexon, the securing of a clean and longer-term balance sheet, and two partnerships with Regeneron and Eden BioCell. We believe it is important to respond urgently," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm. "We want to clarify the record around the programs and assets where we have exclusivity."

Over approximately the last three years, Ziopharm and Intrexon (and later Precigen) mutually agreed to focus their collaborative efforts on four pipeline components: 1. *Sleeping Beauty* TCR-T cell therapy with the National Cancer Institute (NCI); 2. *Sleeping Beauty* CD19 CAR-T at The University of Texas MD Anderson Cancer Center; 3. Ad-RTS-hIL-12 plus veledimex in multi-center trials; and 4. CD33 as a potential CAR target at MD Anderson. In addition, one of the key elements for very-rapid manufacture of T cells genetically modified with the *Sleeping Beauty* platform is membrane-bound interleukin 15, or mbIL15, which was invented by Dr. Cooper's team at MD Anderson and licensed to Ziopharm and Intrexon.

On Oct. 9, 2018, Ziopharm and Intrexon (Precigen) announced details of a new licensing agreement that reset the relationships between the companies. Ziopharm now holds exclusive rights for the treatment of cancer for items 1, 2 and 3 as detailed below:

- For *Sleeping Beauty* intellectual property for all TCRs, including specificity for neoantigens and shared antigens; *Sleeping Beauty*-generated TCR-T cell therapy targeting neoantigens in solid tumors is being developed in collaboration with NCI, which expects to begin treating patients in a phase 1 trial in mid-2019;
- *Sleeping Beauty*-generated CAR-T cell therapy targeting the CD19 antigen with mbIL15 and a kill switch, which is advancing to a clinical trial with two-day T-cell manufacturing in 2H2019;
- Controlled IL-12 platform (Ad-RTS-hIL-12 plus veledimex); Ziopharm has multiple trials with this asset as a monotherapy and in combination with immune checkpoint inhibitors underway and/or planned for 2019.

Ziopharm holds exclusive rights to a second, unnamed target for *Sleeping Beauty* CAR-T therapy and is evaluating its rights to pursue this target following Precigen's assumption of ARES Trading S.A.'s rights under the parties' collaboration agreement. During negotiations Ziopharm agreed to release CD33, the fourth pipeline component, to Precigen.

Precigen cannot use the *Sleeping Beauty* platform intellectual property for TCRs in T cells that has been licensed to Ziopharm, and Precigen cannot research or develop any TCR therapies that target neoantigens (i.e., individual, patient-specific antigens) for three years, under the license agreement. In addition, Precigen cannot use another regulatable switch technology to conditionally express IL-12 for three years for the treatment of cancer.

"Ziopharm's rights to *Sleeping Beauty* TCR- and CAR-T cell therapies, IL-12 with the RheoSwitch and membrane-bound interleukin 15 are clear, and we are committed to protecting our intellectual property and these assets," said David Mauney, M.D., President of Ziopharm.

Dr. Cooper added, "We expect all three programs will be in the clinic in 2019. As for our agreement with Intrexon and Precigen, it is important to remind our shareholders that we sought this separation and we negotiated for the assets we wanted most."

For additional details, including the elimination of approximately $157 million in preferred Ziopharm stock held by Intrexon, please refer to the joint press release issued by Ziopharm and Intrexon (Precigen) on Oct. 9, 2018, the accompanying webcast hosted by Ziopharm the same day and associated SEC filings, including the Company's Form 8-K filed with the SEC on Oct 11, 2018, which describes the material terms of the license agreement.

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 a 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 progress and timing of the development of Ziopharm's research and development programs, including when each of its programs will be in the clinic, and statements regarding future performance. Although Ziopharm's management teams believe 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, 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 for the quarter ended September 30, 2018 and subsequent Quarterly Reports on Form 10-Q filed by Ziopharm with the Securities and Exchange Commission. We are providing this information as of December 27, 2018, 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.

Company contacts:
David Connolly
Vice President, Corporate Communications and Investor Relations
617-502-1881
dconnolly@ziopharm.com

Mike Moyer
Vice President, Portfolio Strategy
617-765-3770
mmoyer@ziopharm.com

Source: ZIOPHARM Oncology Inc