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ZIOPHARM Announces Two Oral Presentations at ASGCT 19th Annual Meeting

BOSTON, April 18, 2016 (GLOBE NEWSWIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq:ZIOP), a biopharmaceutical company focused on new cancer immunotherapies, today announced results from two programs will be presented in oral sessions at the upcoming 19th Annual American Society of Gene and Cell Therapy (ASGCT) Meeting. The first presentation highlights preclinical data from the Company's novel viral gene therapy candidate for the controlled expression of IL-12 in combination with inhibition of programmed cell death protein 1 (PD-1) in a mouse model of glioma. The second presentation highlights preclinical data from the Company's evolution of the *Sleeping Beauty* (SB) non-viral transposon-transposase system in a mouse model of leukemia. The ASGCT meeting will take place May 4-7 at the Marriott Wardman Park Hotel in Washington, D.C.

Title: [Regulated Expression of IL-12 as Gene Therapy Concomitant with Blockade of PD-1 for Treatment of Glioma](#)

Session Title: Cancer-Immunotherapy, Cancer Vaccines II

Date and Time: Friday, May 6, 2016 4:00 PM - 6:00 PM ET

Abstract Number: 509

Room: Washington 1-2

Summary: The utility of clinically-feasible immunotherapy in the investigational treatment of glioma may be improved through combination therapies that enhance cytotoxic immune-activation while concomitantly reducing immunosuppression. ZIOPHARM and Intrexon evaluated the combination of controlled local interleukin 12 (IL-12) administration using a virus (Ad-RTS-IL-12) activated by an oral ligand (veledimex) (Ad +V) and blockade of PD-1 using a checkpoint inhibitor:

- | Results demonstrated that survival of mice treated with Ad +V and anti-PD-1 therapy was superior to either treatment alone;
- | Combination showed 100% survival;
- | Because Ad-RTS-IL-12 and anti-PD-1 are clinically available, these data provide impetus for evaluating this combination immunotherapy in humans;
- | ZIOPHARM plans to initiate a combination study in 2016 and is currently in discussion with partners to provide anti PD-1 therapy.

"The use of PD-1 checkpoint inhibitors in solid tumors has yielded impressive clinical outcomes, yet these results have not yet translated to gliomas, due in part to the immunologic privilege of the central nervous system," said Francois Lebel, M.D., Executive Vice President, Research and Development, Chief Medical Officer at ZIOPHARM. "By combining PD-1 inhibitors, which release a brake on the immune system, with the controlled tumor-directed release of IL-12, which steps on the immune system's accelerator, we see significant anti-tumor activity. These data provide a strong rationale for studying Ad-RTS-IL-12 + veledimex in combination with anti-PD-1 in the clinic, a trial we look forward to initiating later this year."

Title: [Next-Generation Non-Viral Gene Transfer to Redirect T-Cell Specificity](#)

Session Title: Cancer-Immunotherapy, Cancer Vaccines I

Date and Time: Thursday, May 5, 2016 4:00 PM - 5:45 PM ET

Abstract Number: 278

Room: Washington 5-6

Summary: Non-viral gene transfer using the SB transposon/transposase system has been successfully tested in humans to express a chimeric antigen receptor (CAR) to redirect T-cell specificity to CD19. A next-generation SB system has been modified by MD Anderson Cancer Center researchers to improve the design of a CD19-specific CAR as well as reduce the time to manufacture:

- | Changing the "stalk" of the CAR improved the anti-tumor activity of SB-modified T cells;
- | These data support the use of new CAR in an ongoing clinical trial (IND#16474).
- | Decreasing the time the SB-modified T cells were in culture improved the anti-tumor effect;
- | These data provide support for ZIOPHARM's efforts to address the challenges of cost and time of bioprocessing cell therapies;

"Targeting CD19 with CAR-modified T cells is an effective approach to treating CD19-expressing leukemias and lymphomas, as demonstrated by current clinical studies," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of ZIOPHARM. "Fundamental to advancing this approach, and any modified cell-based therapy, into a broadly deployed treatment option is a streamlined and simplified manufacturing process, with a reduction in the associated cost. These data demonstrate our

ability to address these challenges by leveraging the less costly, non-viral *Sleeping Beauty* system and reducing cell culture time, all while improving the effectiveness of the CD19-specific CAR. We look forward to understanding how these next-generation ideas translate into outcomes in an ongoing Phase 1 study and future clinical studies."

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 synthetic 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-IL-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-IL-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. 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.

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