



Positive Preclinical Data for ALKS 4230 Presented at Society for Immunotherapy of Cancer (SITC) 32nd Annual Meeting

November 8, 2017

—Alkermes' Novel Immuno-Oncology Drug Candidate Demonstrated Preferential Expansion and Tumor Infiltration of Select Tumor-Killing Immune Cells in Preclinical Xenograft Model of Metastatic Melanoma —

DUBLIN--(BUSINESS WIRE)--Nov. 8, 2017-- [Alkermes plc](http://www.alkermes.com) (NASDAQ: ALKS) today announced the presentation of positive preclinical data on the company's immuno-oncology drug candidate, ALKS 4230. Data presented by Dr. Brian Gastman of the Cleveland Clinic at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, Md. showed that treatment with ALKS 4230 significantly delayed tumor growth and led to accumulation of tumor-killing T cells in the tumor microenvironment in individualized and humanized melanoma xenograft models of tumor immunology. ALKS 4230 is an engineered fusion protein designed to preferentially bind and signal through the intermediate affinity interleukin-2 (IL-2) receptor complex, thereby selectively activating and increasing the number of immunostimulatory tumor-killing immune cells while avoiding the expansion of immunosuppressive cells that interfere with anti-tumor response.

"These data add to the growing body of evidence supporting the unique profile of ALKS 4230, a novel immuno-oncology candidate designed to harness the IL-2 mechanism in a selective way to enhance anti-tumor activity with the potential for improved safety and tolerability," said Elliot Ehrich, M.D., Executive Vice President, Research and Development of Alkermes. "We continue to progress in the ongoing dose-escalation stage of the phase 1 study for ALKS 4230 in patients with solid tumors, and look forward to determining the optimal dose range of ALKS 4230 and initiating dose expansion in 2018."

In the preclinical data presented at SITC, treatment with ALKS 4230 significantly delayed tumor growth and led to increased numbers of CD8 T cells and non-regulatory CD4 T cells in the tumor microenvironment in individualized melanoma xenograft tumor models. Xenografts were established in immunocompromised mice using tumor cells derived from metastatic melanoma patients, and the mice subsequently received an adoptive transfer of autologous, unexpanded peripheral blood mononuclear cells (PBMC) from the same patient. These data support the rationale for ALKS 4230 as a novel immunotherapeutic for the treatment of melanoma and potentially other solid cancers as well as the strategy of screening individual, patient-specific xenograft models to assess potential treatment efficacy.

A poster on the preclinical data, titled, "A Novel, Individualized Xenograft Model of Cancer Immunotherapy and Tumor Growth Inhibition by ALKS 4230," will be presented by Dr. Brian Gastman of the Cleveland Clinic at SITC in National Harbor, Md. on Friday, Nov. 10, 2017 (Poster #P351). For more information, please visit the conference website at <http://www.sitcancer.org/2017>.

About ALKS 4230

ALKS 4230 is an engineered fusion protein designed to preferentially bind and signal through the intermediate affinity interleukin-2 (IL-2) receptor complex, thereby selectively activating and increasing the number of immunostimulatory tumor-killing immune cells while avoiding the expansion of immunosuppressive cells that interfere with anti-tumor response. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects while overcoming limitations of existing IL-2 therapy, which activates both immunosuppressive and tumor-killing immune cells.

About Alkermes

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning the potential therapeutic value of, and clinical development plans for, ALKS 4230. You are cautioned that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, many of which are beyond the company's control, which could cause actual results to differ materially from those expressed or implied in the forward-looking statements. These risks and uncertainties include, among others, whether preclinical results for ALKS 4230 will be predictive of future clinical study results; whether ALKS 4230 could be shown to be unsafe or ineffective; whether future clinical trials for ALKS 4230 will be initiated or completed on time or at all; changes in the cost, scope and duration of ALKS 4230 clinical trials; and those risks and uncertainties described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended Dec. 31, 2016 and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and Sept. 30, 2017 and in subsequent filings made by the company with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.



View source version on businesswire.com: <http://www.businesswire.com/news/home/20171108005153/en/>

Source: Alkermes plc

Alkermes

For Investors:

Eva Stroynowski, +1 781-609-6823

or

Sandy Coombs, +1 781-609-6377

or

For Media:

Jennifer Snyder, +1 781-609-6166