Alkermes Announces Clinical Trial Collaboration and Supply Agreement With MSD to Evaluate Nemvaleukin Alfa in Combination With KEYTRUDA® in Patients With Platinum-Resistant Ovarian Cancer

April 7, 2021

DUBLIN, April 7, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that it has entered into a clinical trial collaboration and supply agreement with MSD (a tradename of Merck & Co., Inc. Kenilworth, NJ, USA) for a planned phase 3 study to evaluate nemvaleukin alfa ("nemvaleukin", formerly referred to as ALKS 4230), Alkermes' novel investigational engineered interleukin-2 (IL-2) variant immunotherapy, in combination with MSD's KEYTRUDA® (pembrolizumab), in comparison to investigator choice chemotherapy in patients with platinum-resistant ovarian cancer. Under the terms of the agreement, Alkermes is responsible for conducting the phase 3 study, which is planned to initiate in the second half of 2021.

"We are pleased to collaborate with MSD to evaluate nemvaleukin in combination with KEYTRUDA in patients with platinum-resistant ovarian cancer, a patient population for which there are limited treatment options available and overall survival remains low. Importantly, there are no anti-PD-1 treatments currently approved for this tumor type," said Jessicca Rege, Ph.D., Vice President, Head of Oncology at Alkermes. "Nemvaleukin in combination with KEYTRUDA has demonstrated antitumor activity in heavily pre-treated patients with platinum-resistant ovarian cancer in the ongoing ARTISTRY-1 study, with durable and deepening responses observed. We look forward to initiating this phase 3 study to further evaluate the potential clinical utility of this combination in this tumor type and advancing our interactions with regulatory authorities related to potential registration strategies for the combination in platinum-resistant ovarian cancer."

About nemvaleukin alfa
Nemvaleukin is an investigational, novel, engineered fusion protein comprised of modified interleukin-2 (IL-2) and the high affinity IL-2 alpha receptor chain, designed to selectively expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by preferentially binding to the intermediate-affinity IL-2 receptor complex. The selectivity of nemvaleukin is designed to leverage the proven antitumor effects of existing IL-2 therapy while mitigating certain limitations.

About the ARTISTRY Clinical Development Program
ARTISTRY is an Alkermes-sponsored clinical development program evaluating nemvaleukin in patients with advanced solid tumors.

ARTISTRY-1 and ARTISTRY-2 are phase 1/2 studies evaluating the safety, tolerability, efficacy and pharmacokinetic and pharmacodynamic effects of nemvaleukin in patients with refractory advanced solid tumors, in both monotherapy and combination settings with the PD-1 inhibitor pembrolizumab (KEYTRUDA®). In ARTISTRY-1, nemvaleukin is administered as an intravenous infusion daily for five consecutive days, followed by an off-treatment period. In the ongoing phase 2 efficacy expansion stage of ARTISTRY-2, nemvaleukin is administered subcutaneously once every seven days.

ARTISTRY-3 is a phase 2 study evaluating the clinical and immunologic effects of intravenous nemvaleukin monotherapy on the tumor microenvironment of a variety of advanced, malignant solid tumors.

About Alkermes plc
Alkermes plc is a fully-integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on addiction and schizophrenia, and a pipeline of product candidates in development for schizophrenia, bipolar I disorder, neurodegenerative disorders and cancer. 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 nemvaleukin alfa ("nemvaleukin", formerly referred to as ALKS 4230) as a cancer immunotherapy when used in combination with KEYTRUDA for the treatment of patients with platinum-resistant ovarian cancer (PROC); plans for initiating a phase 3 study in the second half of 2021; and plans to advance interactions with regulatory authorities related to potential registration strategies for the combination in platinum-resistant ovarian cancer. 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 they are necessarily subject to a high degree of uncertainty and risk. Actual results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others, whether nemvaleukin, as a monotherapy or in combination, could be shown to be unsafe or ineffective; whether preclinical results and data from ongoing clinical studies for nemvaleukin will be predictive of future or final results from such studies, results of future clinical studies or real-world results; whether future clinical trials or future stages of ongoing clinical trials for nemvaleukin will be initiated or completed on time or at all; changes in the cost, scope and duration of, and clinical trial operations for, development activities for nemvaleukin, including changes relating to the impact of the novel coronavirus (COVID-19) pandemic; 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, 2020 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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

Alkermes Contacts:
For Investors: Sandy Coombs, +1 781 609 6377
For Media: Sourojit Bhowmick, Ph.D. +1 781 609 6397

View original content to download multimedia:http://www.prnewswire.com/news-releases/alkermes-announces-clinical-trial-collaboration-and-supply-agreement-with-msd-to-evaluate-nemvaleukin-alfa-in-combination-with-keytruda-in-patients-with-platinum-resistant-ovarian-cancer-301263617.html

SOURCE Alkermes plc