Alkermes Initiates ARTISTRY-6 Trial of Nemvaleukin Alfa Monotherapy in Patients With Melanoma

April 27, 2021

DUBLIN, April 27, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced the initiation of ARTISTRY-6, a global phase 2 trial evaluating the anti-tumor activity, safety and tolerability of nemvaleukin alfa (nemvaleukin) monotherapy in patients with melanoma who have been previously treated with anti-PD-(L)1 therapy. The study will evaluate intravenously administered (IV) nemvaleukin in patients with mucosal melanoma and subcutaneously administered (SC) nemvaleukin in patients with advanced cutaneous melanoma. Nemvaleukin, Alkermes' lead immuno-oncology candidate, is a novel, investigational engineered interleukin-2 (IL-2) variant immunotherapy. Nemvaleukin was granted orphan drug designation for the treatment of mucosal melanoma by the U.S. Food and Drug Administration (FDA) in March 2021.

"The initiation of the ARTISTRY-6 study represents a significant milestone in the nemvaleukin development program, building on the early signals of anti-tumor activity observed with IV nemvaleukin in melanoma," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President at Alkermes. "Consistent with our strategy to study nemvaleukin in difficult-to-treat cancers with clear unmet need, we look forward to further evaluating the potential clinical utility of nemvaleukin monotherapy in mucosal melanoma, a rare and aggressive form of melanoma that has very limited treatment options. We recently discussed with the FDA a potential filing pathway in mucosal melanoma, pending review of data that emerge from ARTISTRY-6."

ARTISTRY-6 is designed to evaluate the anti-tumor activity, safety and tolerability of IV nemvaleukin in patients with mucosal melanoma. The study also includes a cohort of patients with advanced cutaneous melanoma who will receive SC nemvaleukin with intent to establish monotherapy proof-of-concept with SC dosing. The primary endpoint of ARTISTRY-6 is centrally-assessed overall response rate based on Response Evaluation Criteria in Solid Tumors (RECIST) 1.1, to be evaluated separately for patients with mucosal or cutaneous melanoma. The secondary endpoints include safety and tolerability, duration of response, progression-free survival, disease control rate and time to response based on RECIST 1.1. Additionally, the phase 2 study will assess health-related quality of life, and pharmacokinetic and pharmacodynamic effects of IV and SC nemvaleukin monotherapy. The study is planned to enroll approximately 110 patients. Patients will be enrolled into one of two cohorts: patients with advanced mucosal melanoma will receive 6 µg/kg/day IV nemvaleukin for 5 consecutive days every 3 weeks, and patients with advanced cutaneous melanoma will receive 3 mg SC nemvaleukin once every 7 days.

More information can be found at www.clinicaltrials.gov, identifier: NCT04830124.

About Nemvaleukin alfa ("nemvaleukin", formerly ALKS 4230)
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 anti-tumor 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 alfa as a potential immunotherapy for cancer. The ARTISTRY program is comprised of multiple clinical trials evaluating intravenous and subcutaneous dosing of nemvaleukin, both as a monotherapy and in combination with the anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors. Ongoing trials include: ARTISTRY-1, ARTISTRY-2, ARTISTRY-3 and ARTISTRY-6.

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 monotherapy immunotherapy in patients with melanoma; the clinical trial design for ARTISTRY-6; and potential filing pathways for nemvaleukin in mucosal melanoma. 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 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-initiates-artistry-6-trial-of-nemvaleukin-alfa-monotherapy-in-patients-with-melanoma-301276747.html

SOURCE Alkermes plc