Alkermes Announces FDA Orphan Drug Designation for Nemvaleukin Alfa for Treatment of Mucosal Melanoma

March 11, 2021

DUBLIN, March 11, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that nemvaleukin alfa ("nemvaleukin", formerly referred to as ALKS 4230), the company's investigational engineered interleukin-2 (IL-2) variant immunotherapy, has been granted orphan drug designation for the treatment of mucosal melanoma by the U.S. Food and Drug Administration (FDA).

"This orphan drug designation is an important milestone for the nemvaleukin alfa program and underscores nemvaleukin's potential clinical utility in mucosal melanoma, a particularly aggressive form of melanoma for which treatment options remain limited," said Jessicca Rege, Ph.D., Vice President, Head of Oncology at Alkermes. "The accumulating data from the nemvaleukin program have continued to support the clinical profile we anticipated in targeting the IL-2 pathway, and we look forward to continuing our momentum with the ARTISTRY development program this year."

Under the Orphan Drugs Act (ODA), the FDA may grant orphan drug designation to drugs and biologics that are intended to treat diseases or conditions affecting fewer than 200,000 people in the U.S. Orphan drug designation qualifies the drug developer for a variety of development incentives, including tax credits for qualified clinical testing, exemptions from certain FDA application fees, and seven years of market exclusivity, if approved. For more information on orphan drug designation, please visit the FDA website, available at https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products.

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. In ARTISTRY-2, nemvaleukin is administered subcutaneously and is being evaluated with once-weekly and once-every-three-week dosing schedules.

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

About Alkermes
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 as a cancer immunotherapy, including in the treatment of mucosal melanoma; and the company's expectations of continued momentum for the ARTISTRY development program this year. 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 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 impacts of the COVID-19 pandemic on such operations and activities; 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.

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-fda-orphan-drug-designation-for-nemvaleukin-alfa-for-treatment-of-mucosal-melanoma-301245191.html

SOURCE Alkermes plc