Alkermes Receives FDA Fast Track Designation for Nemvaleukin Alfa for the Treatment of Mucosal Melanoma

August 2, 2021

DUBLIN, Aug. 2, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to nemvaleukin alfa (nemvaleukin), the company's novel, investigational engineered interleukin-2 (IL-2) variant immunotherapy, for the treatment of mucosal melanoma. Earlier this year, the FDA also granted orphan drug designation to nemvaleukin for the treatment of mucosal melanoma. The company recently initiated enrollment in ARTISTRY-6, a global phase 2 trial evaluating the anti-tumor activity, safety and tolerability of nemvaleukin monotherapy in patients with melanoma who have been previously treated with anti-PD-(L)1 therapy. The study is evaluating intravenously administered nemvaleukin in patients with mucosal melanoma and subcutaneously administered nemvaleukin in patients with advanced cutaneous melanoma.

"Receiving Fast Track designation from the FDA for nemvaleukin for the treatment of mucosal melanoma is an important milestone for the nemvaleukin development program and underscores nemvaleukin's potential clinical utility to address an unmet medical need in this difficult-to-treat tumor type," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "We are committed to advancing this important research in mucosal melanoma, a rare and aggressive form of melanoma for which there are very limited treatment options, particularly for those patients previously treated with checkpoint inhibitors."

Fast Track is an FDA process designed to facilitate the development and expedite the review of potential therapies that seek to treat serious conditions and fill an unmet medical need. A drug candidate that receives Fast Track designation is eligible for more frequent communication with the FDA throughout the drug development process and a rolling and/or priority review of its marketing application if relevant criteria are met. For more information on Fast Track designation, please visit the FDA's website, available at https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

More information on the ARTISTRY-6 study can be found at www.clinicaltrials.gov, identifier: NCT04830124.

About Nemvaleukin Alfa ("nemvaleukin")
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 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, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for 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, whether as monotherapy or in combination and whether delivered intravenously or subcutaneously, as a cancer immunotherapy, including in the treatment of mucosal melanoma; the expected benefits of FDA Fast Track designation; and the company's commitment to advancing research 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 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.

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