

Alkermes to Present Two Posters on Investigational Immuno-oncology Candidate, Nemvaleukin Alfa, at the 2021 European Society for Medical Oncology (ESMO) Virtual Congress

September 13, 2021

DUBLIN, Sept. 13, 2021 /PRNewswire/ -- <u>Alkermes plc</u> (Nasdaq: ALKS) today announced two poster presentations related to nemvaleukin alfa (nemvaleukin), the company's novel, investigational, engineered interleukin-2 (IL-2) variant immunotherapy, at the 2021 European Society for Medical Oncology (ESMO) Virtual Congress, taking place Sept. 16-21, 2021. The presentations will include a trial-in-progress poster for 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, with or without anti-CTLA-4 therapy, and a poster showing data from a preclinical study that evaluated the anti-tumor efficacy of a mouse ortholog of nemvaleukin as monotherapy and in combination with chemotherapy in a murine model of small cell lung cancer.

"We're pleased to share updates from the nemvaleukin development program with the scientific and medical community at ESMO. This year's posters include information on our ongoing ARTISTRY-6 clinical trial in melanoma, which is designed to support potential registration in mucosal melanoma, and data from a preclinical study that investigated the potential of nemvaleukin in combination with chemotherapy," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "We look forward to continuing to explore nemvaleukin's potential as a novel, differentiated therapy for patients with high unmet need across a wide array of tumor types."

Details of the presentations are as follows:

Abstract: 834

Title: ARTISTRY-6: Nemvaleukin alfa monotherapy in patients with advanced mucosal and cutaneous melanoma

Presenter: Richard D. Carvajal, M.D., Director of Experimental Therapeutics and Director of the Melanoma Service at Columbia University Medical Center

Presentation Date: The poster presentation will be available on demand to attendees beginning Sept. 16, 2021.

Abstract: 3326

Title: Anti-tumor efficacy and immune profiling of the mouse ortholog of nemvaleukin alfa, a novel engineered IL-2 fusion protein, in an orthotopic mouse model of small cell lung cancer alone or in combination with standard chemotherapy

Presenter: Yuanwang Pan, Ph.D., Postdoctoral Fellow, Immuno-Oncology, Laura and Isaac Perlmutter Cancer Center, New York University Grossman School of Medicine, NYU Langone Health

Presentation Date: The poster presentation will be available on demand to attendees beginning Sept. 16, 2021.

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 preferentially expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by selectively 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 in the ARTISTRY program include: <u>ARTISTRY-1</u>, <u>ARTISTRY-2</u>, <u>ARTISTRY-3</u> and <u>ARTISTRY-6</u>.

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, as a cancer immunotherapy across a wide array of tumor types, including in the treatment of melanoma and small cell lung cancer; and plans to use data from ARTISTRY-6 to support nemvaleukin's potential registration 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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