Alkermes Awarded Innovation Passport Designation by the MHRA (UK) for Nemvaleukin Alfa for the Treatment of Mucosal Melanoma

January 17, 2023

— Designation Marks Entry Point into MHRA's Innovative Licensing and Access Pathway (ILAP) Program in the UK —

DUBLIN, Jan. 17, 2023 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that nemvaleukin alfa (nemvaleukin), the company's investigational, novel engineered interleukin-2 (IL-2) variant immunotherapy, has been granted an Innovation Passport for the treatment of mucosal melanoma under the Innovative Licensing and Access Pathway (ILAP) by the Medicines and Healthcare products Regulatory Agency (MHRA), the regulatory body of the United Kingdom (UK). The Innovation Passport designation is the entry point to the ILAP, which aims to accelerate time to market and facilitate patient access to medicines in the UK for life-threatening or seriously debilitating conditions, or conditions for which there is a significant patient or public health need. Benefits of ILAP include access to a range of development tools, such as the potential for a 150-day accelerated Marketing Authorization Application (MAA) assessment, rolling review and a continuous benefit-risk assessment.

"We believe in the potential of nemvaleukin to help address persistent unmet needs faced by patients with mucosal melanoma," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "The granting of the Innovation Passport represents an exciting step in the clinical development program of our IL-2 candidate, and we look forward to working closely with the MHRA and the ILAP partner agencies in an effort to bring nemvaleukin to people living with mucosal melanoma in the UK."

The U.S. Food and Drug Administration previously granted Orphan Drug designation and Fast Track designation to nemvaleukin for the treatment of mucosal melanoma.

About Innovation Passport and ILAP

ILAP was launched by the MHRA in January 2021 with an aim to accelerate the development of and facilitate patient access to medicines. The Innovation Passport is granted by the UK's ILAP Steering Group, which consists of representatives from MHRA, the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC), the All Wales Therapeutics and Toxicology Centre (AWTTC) and the National Health Service (NHS) England. It is the first step in the ILAP process and awarded to companies developing therapies with the potential to offer significant benefit to patients who have conditions that are life-threatening or seriously debilitating. A single Innovation Passport can cover multiple future indications for the same molecule.

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. Nemvaleukin is currently the most advanced IL-2-based immuno-therapy in clinical development, with two actively recruiting, potentially registrational studies, ARTISTRY-6 and ARTISTRY-7 in mucosal melanoma and platinum-resistant ovarian cancer, respectively.

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. Trials in the ARTISTRY program include: ARTISTRY-1, ARTISTRY-2, ARTISTRY-3, ARTISTRY-6 and ARTISTRY-7.

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 alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurological disorders and cancer. Headquartered in Dublin, Ireland, Alkermes has a research and development 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 therapeutic and commercial potential of nemvaleukin as an immunotherapy, including for mucosal melanoma and 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 could be shown to be unsafe or ineffective; whether results and data from 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, 2021, and in subsequent filings made by the company with the U.S. Securities and Exchange

Commission (SEC), including the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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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