Alkermes Presents New Nemvaleukin Alfa Monotherapy Data at the American Society of Clinical Oncology Genitourinary Cancers Symposium

February 17, 2022

- Data From ARTISTRY-1 Clinical Trial Highlight Single-Agent, Anti-Tumor Activity of Nemvaleukin in Patients With Renal Cell Carcinoma -

DUBLIN, Feb. 17, 2022 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today presented new data from the ongoing phase 1/2 ARTISTRY-1 clinical trial for nemvaleukin alfa (nemvaleukin), the company's novel, investigational, engineered interleukin-2 (IL-2) variant immunotherapy. The data were presented at the American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, taking place Feb. 17-19, 2022.

The presentation includes updated efficacy and safety data from the monotherapy arm of ARTISTRY-1, in which single-agent, anti-tumor activity of intravenous (IV) nemvaleukin was observed in patients with advanced renal cell carcinoma (RCC), including patients who were checkpoint inhibitor (CPI)-pretreated.

"Nemvaleukin's single-agent activity is an important differentiating feature in the IL-2 space and suggests that nemvaleukin may contribute clinical benefit when used in combination regimens with other cancer treatments like checkpoint inhibitors," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "Together with the objective responses previously reported in the melanoma cohort of this study, these data in renal cell carcinoma show nemvaleukin's monotherapy activity in two tumor types where high-dose IL-2 is approved, thus validating its novel molecular design."

Data highlights from the ASCO GU poster presentation include:

ARTISTRY-1, IV Nemvaleukin (6 µg/kg) Monotherapy Arm, RCC Patients
The ARTISTRY-1 monotherapy RCC cohort included 27 patients with advanced RCC, 56% of whom were CPI-pretreated. As of the Oct. 29, 2021 data cutoff:

- Nemvaleukin monotherapy induced robust expansion of $CD8^+$ T and natural killer (NK) cells, with minimal effect on regulatory T cells (T_{regs}).
- Among 23 evaluable patients (with at least one post-baseline scan):
  - Four patients, all of whom were CPI-pretreated, achieved a partial response (one unconfirmed) and three of these patients continued on monotherapy.
  - Decreases in target lesions of up to 60% were observed.
  - Stable disease was observed in 10 patients.

Safety among these patients with advanced RCC was consistent with that which was previously reported for the IV nemvaleukin monotherapy-treated population in the ARTISTRY-1 study. Fever, chills, nausea and anemia were the most frequently reported adverse events (AEs), regardless of causality. Chills and anemia were the most commonly reported treatment-related AEs of grade ≥3. There were no deaths due to treatment-related AEs.

Details of the presentation are available on the ASCO GU website at https://conferences.asco.org/gu/attend

Abstract: 330
Title: Nemvaleukin Alfa in Patients With Advanced Renal Cell Carcinoma: ARTISTRY-1
Presenter: Emiliano Calvo, M.D., Ph.D., Medical Oncologist and Director of Clinical Research at the START Madrid-Centro Integral Oncológico Clara Campal Hospital, Madrid, Spain
Presentation Date: The poster, along with a pre-recorded presentation, will be available on the ASCO GU virtual meeting platform beginning Feb. 17, 2022.

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 Nemvaleukin 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: 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 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 and utility of nemvaleukin as an immunotherapy, whether used as monotherapy or in combination. 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 ongoing 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), 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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