Alkermes Initiates ARTISTRY-7 Phase 3 Trial of Nemvaleukin Alfa in Patients With Platinum-Resistant Ovarian Cancer

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- Study to Evaluate Intravenous Nemvaleukin in Combination With Pembrolizumab Compared to Investigator's Choice Chemotherapy -

DUBLIN, Oct. 26, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced the initiation of ARTISTRY-7, a global phase 3, open-label, randomized trial evaluating the anti-tumor activity and safety of intravenously administered (IV) nemvaleukin alfa (nemvaleukin), in combination with pembrolizumab, compared to investigator's choice chemotherapy, in patients with platinum-resistant ovarian cancer. Nemvaleukin, Alkermes' lead immuno-oncology candidate, is a novel, investigational, engineered interleukin-2 (IL-2) variant immunotherapy. As previously announced, ARTISTRY-7 is being conducted in collaboration with MSD (a tradename of Merck & Co., Inc. Kenilworth, NJ, USA), which is providing KEYTRUDA® (pembrolizumab) for the study. In addition, Alkermes is working with The GOG Foundation, Inc. (GOG) and the European Network of Gynaecological Oncological Trial groups (ENGOT) to conduct the study. The U.S. Food and Drug Administration recently granted Fast Track designation to nemvaleukin in combination with pembrolizumab for the treatment of platinum-resistant ovarian cancer.

"The initiation of our phase 3 study of nemvaleukin in platinum-resistant ovarian cancer is an important milestone for the nemvaleukin clinical development program and reflects our commitment to focusing on the high unmet need of patients living with difficult-to-treat cancers such as platinum-resistant ovarian cancer," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "ARTISTRY-7 is designed to build upon the durable and deepening responses observed in heavily pre-treated patients with platinum-resistant ovarian cancer in the ongoing ARTISTRY-1 study. We look forward to sharing updates from ARTISTRY-7 as the study progresses and as we advance toward potential registration."

ARTISTRY-7 is a global phase 3, open-label, randomized study designed to evaluate the anti-tumor activity and safety of IV nemvaleukin in combination with pembrolizumab compared to investigator's choice chemotherapy, with additional nemvaleukin and pembrolizumab monotherapy arms, in patients with platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer. The primary endpoint of ARTISTRY-7 is progression-free survival as assessed by the investigator, based on Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. Additional endpoints include objective response rate, overall survival, disease control rate, duration of response, time to response, cancer antigen-125 response, pharmacokinetics (PK)/ pharmacodynamics (PD) and safety. The study is expected to enroll approximately 376 patients. Patients will be randomized to one of four treatment arms to receive nemvaleukin and pembrolizumab combination therapy, pembrolizumab monotherapy, nemvaleukin monotherapy, or investigator's choice chemotherapy.

More information can be found at www.clinicaltrials.gov (NCT05092360, GOG-3063, ENGOT-ov68)

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: 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 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.

About The GOG Foundation, Inc. (www.gog.org)
The GOG Foundation, Inc. (GOG) is a not-for profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials, development, execution, analysis and distribution of results. The GOG Foundation is the only clinical trialist group in the United States that focuses its research on patients with pelvic malignancies, such as cancers of the ovaries, uterus, cervix, vagina, and vulva.

The GOG Partners, a GOG Foundation program, is structured to work directly with pharmaceutical organizations and operate clinical trials outside the National Cancer Institute (NCI) framework. The GOG Partners shares the same mission of the GOG Foundation dedicated to transforming the care in Gynecologic Oncology. By providing an alternative venue for patient accrual and site infrastructure support, GOG Partners has helped provide additional trials and opportunities for patients outside the national gynecologic clinical trials network.

About ENGOT

ENGOT (European Network for Gynaecological Oncological Trial groups) is a research network of the European Society of Gynecological Oncology (ESGO) and was founded in 2007. ENGOT is a platform that guarantees that the European spirit and culture is incorporated into the medical progress in gynaecological oncology, and that European patients and countries can participate in an active way in clinical research and progress. Currently, ENGOT includes 21 cooperative groups from 25 European countries.

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 for the treatment of difficult-to-treat cancers such as platinum-resistant ovarian cancer (PROC); plans for the design and conduct of ARTISTRY-7; and plans to provide updates from ARTISTRY-7 and to advance nemvaleukin toward potential registration. 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, whether used as monotherapy or in combination, 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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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