Alkermes Initiates Clinical Study of ALKS 4230 Administered Subcutaneously in Patients With Advanced Solid Tumors

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-- Once-Weekly and Once-Every-Three-Week Dosing of ALKS 4230 to be Evaluated as Monotherapy and in Combination With Pembrolizumab --

-- ARTISTRY-2 is Second Clinical Study to Initiate in ARTISTRY Clinical Development Program for ALKS 4230 --

DUBLIN, Feb. 26, 2019 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced the initiation of ARTISTRY-2, a new clinical study of ALKS 4230 administered subcutaneously as monotherapy and in combination with the PD-1 inhibitor KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors. The study will explore the safety, tolerability and efficacy of ALKS 4230 administered subcutaneously and assess once-weekly and once-every-three-week dosing schedules. ALKS 4230 is a novel, engineered fusion protein designed to selectively activate tumor-killing immune cells while avoiding the expansion of immunosuppressive cells by preferentially binding to the intermediate-affinity interleukin-2 (IL-2) receptor complex. Pembrolizumab is an anti-PD-1 therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells.

ARTISTRY-2, a phase 1/2 study, will be conducted in two stages: dose-escalation followed by dose-expansion. The dose-escalation stage is designed to evaluate the safety and tolerability of ascending doses of ALKS 4230 administered subcutaneously once-weekly and once-every-three-weeks as both lead-in monotherapy and in combination with pembrolizumab. Following identification of the optimal dose and recommended dosing schedule, the dose-expansion stage of the study will evaluate ALKS 4230 administered subcutaneously in combination with pembrolizumab in patients with advanced solid tumors. The dose-expansion stage will evaluate overall response rate, duration of response, non-progression rate at specific time points and overall survival.

"The initiation of our clinical subcutaneous dosing study represents an important milestone for the ALKS 4230 program as we explore new regimens that may offer patients a more convenient alternative to daily IV dosing that is complementary to checkpoint inhibitor regimens," said Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. "Based on the emerging profile of ALKS 4230, we've rapidly expanded our clinical development program in recent months to evaluate combination therapy, potential efficacy in new tumor types and dosing optionality. The expansion of this program reflects our belief in the significant potential of ALKS 4230 and our recognition of the urgent and persistent need that exists for patients with cancer."

Data presented at the Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting demonstrated that subcutaneous administration of ALKS 4230 in non-clinical models achieved similar total systemic exposure of ALKS 4230 compared to intravenous (IV) administration, yet with less frequent dosing and a lower C_{max}, leading to similar expansion of total $CD8^+$ T cell and natural killer (NK) cell populations. These data support further clinical evaluation of subcutaneous administration of ALKS 4230 as an alternative to IV dosing.

About ALKS 4230

ALKS 4230 is a novel, engineered fusion protein designed to selectively activate tumor-killing immune cells while avoiding the expansion of immunosuppressive cells by preferentially binding to the intermediate-affinity interleukin-2 (IL-2) receptor complex. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects of existing IL-2 therapy while mitigating certain limitations.

About the ARTISTRY Clinical Program

ARTISTRY is an Alkermes-sponsored clinical program evaluating ALKS 4230 in patients with advanced solid tumors. ARTISTRY-1 is an ongoing phase 1 study in which ALKS 4230 is administered as an intravenous infusion daily for five consecutive days. ARTISTRY-1 has three distinct stages: an ongoing monotherapy dose-escalation stage, a planned monotherapy dose-expansion stage and an ongoing combination therapy stage with pembrolizumab. ARTISTRY-2 is the second clinical study to initiate in the ARTISTRY clinical development program for ALKS 4230.

About Alkermes

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction, multiple sclerosis and oncology. 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 and commercial value of ALKS 4230, including in combination with pembrolizumab; and clinical development plans for evaluation of ALKS 4230 both as a monotherapy and in combination with pembrolizumab, including details of the ongoing and planned stages of the ARTISTRY-1 phase 1 study and the newly initiated ARTISTRY-2 phase 1/2 study. 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 are subject to a variety of risks and uncertainties, many of which are beyond the company's control, which could cause actual results to differ materially from those expressed or implied in the forward-looking statements. These risks and uncertainties include, among others, whether preclinical and early clinical results for ALKS 4230, as a monotherapy or in combination with pembrolizumab, will be predictive of future clinical study results; whether ALKS 4230, as a monotherapy or in combination, could be shown to be unsafe or ineffective; whether future clinical trials or future stages of ongoing clinical trials for ALKS 4230, as a monotherapy or in combination with pembrolizumab, will be initiated or completed on time or at all; changes in the cost, scope and duration of development activities for ALKS 4230; 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, 2018 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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