Alkermes Announces Clinical Collaboration With Fred Hutchinson Cancer Research Center for Novel Immuno-Oncology Drug Candidate ALKS 4230

October 21, 2019

-- Planned Phase 2 Multi-Site Trial to Evaluate ALKS 4230 in Combination With Pembrolizumab in Patients With Advanced or Recurrent Head and Neck Squamous Cell Cancer --

DUBLIN, Oct. 21, 2019 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that it has entered into a clinical research collaboration with Fred Hutchinson Cancer Research Center (Fred Hutch) for ALKS 4230, Alkermes' immuno-oncology drug candidate. ALKS 4230 is a novel, engineered fusion protein designed to selectively expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by preferentially binding to the intermediate-affinity interleukin-2 (IL-2) receptor complex.

The planned phase 2 multi-site trial, ION-01, is designed to estimate the response rate to ALKS 4230 in combination with the anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced or recurrent head and neck squamous cell cancer who did not achieve complete remission with an anti-PD-(L)1 antibody treatment. Secondary objectives include evaluation of the duration of response, progression-free survival, time to progression and overall survival of patients with advanced or recurrent head and neck squamous cell cancer receiving treatment with ALKS 4230 in combination with pembrolizumab. As an exploratory objective, the ION-01 study will assess the tumor microenvironment using paired tumor biopsies to evaluate potential predictive biomarkers for response to the addition of ALKS 4230. This multi-site study is designed to leverage the scientific, clinical and management resources of the Immune Oncology Network (ION), a network of foremost academic immunologists at top North American universities and cancer centers. The study is expected to initiate in the fourth quarter of 2019.

"We are honored to collaborate with Fred Hutch, given its commitment to improving outcomes and advancing care for people living with cancer," said Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. "We're encouraged by the profile emerging from the preclinical and initial clinical data for ALKS 4230 and are eager to explore whether this novel investigational drug may improve the therapeutic benefit of checkpoint inhibition with pembrolizumab, in patients with head and neck cancers. The ION-01 study, along with our ongoing ARTISTRY clinical development program, offers the opportunity to strengthen and advance our scientific and clinical understanding of ALKS 4230 and its potential role in treating cancer patients with high unmet needs."

About ALKS 4230

ALKS 4230 is a novel, engineered fusion protein comprised of modified interleukin-2 (IL-2) and the high affinity IL-2 alpha receptor chain, designed to selectively expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by preferentially binding to the intermediate-affinity 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 Development Program

ARTISTRY is an Alkermes-sponsored clinical development program evaluating ALKS 4230 in patients with advanced solid tumors. ARTISTRY-1 is an ongoing phase 1/2 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 recently-initiated monotherapy expansion stage and an ongoing combination therapy stage with the PD-1 inhibitor KEYTRUDA® (pembrolizumab) in patients with select advanced solid tumors. ARTISTRY-2 is an ongoing phase 1/2 study of ALKS 4230 administered subcutaneously as monotherapy and in combination with pembrolizumab in patients with advanced solid tumors. ARTISTRY-2 is designed to explore the safety, tolerability and efficacy of ALKS 4230 administered subcutaneously and assess once-weekly and once-every-three-week dosing schedules.

About Alkermes

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases and oncology. 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 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 and commercial value of ALKS 4230, including in combination with pembrolizumab; clinical development plans for ALKS 4230, including the timing and details of the planned ION-01 study of ALKS 4230 in combination with pembrolizumab; and the potential benefits that may be achieved through the clinical research collaboration described in this press release. 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 preliminary or final data from preclinical and early clinical studies of ALKS 4230, as a monotherapy or in combination with pembrolizumab, will be predictive of future data from the same studies, results of future clinical studies or real-world 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, will be initiated or completed on time or at all; changes in the cost, scope and duration of development activities for ALKS 4230; whether the potential benefits of the clinical research collaboration described in this press release will be achieved; 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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