



## **Alkermes Announces Initiation of Phase 1 Clinical Study of Immuno-Oncology Drug Candidate ALKS 4230**

May 25, 2016

*—Novel Selective Effector Cell Activator (SECA™) Protein Designed for Targeted IL-2 Receptor Activation to Enhance Tumor-Killing Immune Cells—*

DUBLIN--(BUSINESS WIRE)--May 25, 2016-- [Alkermes plc](#) (NASDAQ: ALKS) today announced the initiation of a phase 1 clinical study of the company's immuno-oncology drug candidate, ALKS 4230 (formerly referred to as RDB 1450), a novel Selective Effector Cell Activator (SECA™) protein designed for targeted interleukin-2 (IL-2) receptor activation. The multi-center phase 1 study is designed to evaluate the safety, tolerability and immunological-pharmacodynamic effects of ALKS 4230 in the treatment of patients with solid tumors.

The phase 1 study will be conducted in two stages: a dose-escalation stage followed by a dose-expansion stage. In the first stage of the study, ALKS 4230 will be administered as an intermittent intravenous infusion with ascending doses in patients with solid tumors who are refractory or intolerant to established therapies. This first stage of the study is designed to determine a maximum tolerated dose, and to identify the optimal dose range of ALKS 4230 based on measures of immunological-pharmacodynamic effects. Following the identification of the optimal dose range of ALKS 4230 in the first stage of the study, the dose-expansion stage of the study will evaluate ALKS 4230 in patients with selected solid tumor types. Initial results from the first stage of the phase 1 study are expected in 2017.

"ALKS 4230 is a unique immuno-oncology candidate that is designed to harness the IL-2 mechanism in a selective way that enhances tumor-killing immune cells, so that a patient's own immune system can be activated in order to fight cancer more effectively," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "We have designed this initial clinical study of ALKS 4230 to be highly informative and to position us for phase 2 studies, including those that may include ALKS 4230 in combination with other immuno-oncology therapies. We are excited about the start of the clinical program and the potential for ALKS 4230 to make an impact for patients with cancer."

### **About ALKS 4230 and the SECA™ Immuno-Oncology Program**

ALKS 4230 is a novel selective effector cell activator (SECA™) protein designed to preferentially bind and signal through the intermediate affinity interleukin-2 (IL-2) receptor complex, thereby selectively activating and increasing the number of immunostimulatory tumor-killing immune cells while avoiding the expansion of immunosuppressive cells that interfere with anti-tumor response. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects while overcoming limitations of existing IL-2 therapy which activates both immunostimulatory and immunosuppressive receptors.

SECA proteins are engineered using Alkermes' proprietary PICASSO™ circular permutation technology leveraging human protein biology to achieve their unique mechanism of action.

### **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 and multiple sclerosis. 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](http://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 value, clinical development plans and commercial potential for ALKS 4230. 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 will be predictive of future clinical study results; whether ALKS 4230 could be shown to be unsafe or ineffective; whether future clinical trials for ALKS 4230 will be initiated or completed on time or at all; changes in the cost, scope and duration of ALKS 4230 clinical trials; and those risks described in the Alkermes plc Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2015 and in any other 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](http://www.sec.gov). The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking information contained in this press release.

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