Alkermes Announces First Subject Dosed in Phase 1 Study of ALKS 1140 for the Treatment of Neurodegenerative and Neurological Disorders

November 11, 2021

DUBLIN, Nov. 11, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced dosing of the first subject in a phase 1 study evaluating the safety and tolerability of ALKS 1140 in healthy adults. ALKS 1140 is a novel, investigational CoREST-selective (co-repressor of repressor element-1 silencing transcription factor) HDAC (histone deacetylase) inhibitor candidate for the treatment of neurodegenerative and neurological disorders. ALKS 1140 is designed to increase functional synaptic connections and synaptic integrity in the brain.

"We are pleased to advance ALKS 1140, Alkermes' first development candidate nominated from our HDAC inhibitor platform, into first-in-human studies," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. "Improving synaptic function may slow progression, and preserve cognitive and functional abilities, across many neurological disorders, an area with significant unmet patient need. ALKS 1140 presents an opportunity to harness the prosynaptic effects of CoREST-selective HDAC inhibitors, and we look forward to further characterizing ALKS 1140's safety and tolerability profile as we initiate our clinical program."

The primary objectives of this first-in-human, phase 1, two-part study are to assess the safety and tolerability of single (part 1) and multiple (part 2) ascending oral doses of ALKS 1140 in healthy adults. The study is also designed to characterize the pharmacokinetic and pharmacodynamic profile of ALKS 1140. The study is expected to enroll up to 80 healthy volunteers at a clinical study site in Australia.

More information can be found at www.clinicaltrials.gov, identifier: NCT05019105.

About ALKS 1140
ALKS 1140 is a novel, investigational CoREST-selective (co-repressor of repressor element-1 silencing transcription factor) HDAC (histone deacetylase) inhibitor candidate for the treatment of neurodegenerative and neurological disorders. ALKS 1140 is designed to increase functional synaptic connections and synaptic integrity in the brain.

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.

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 ALKS 1140 for the treatment of neurodegenerative and neurological disorders; and the company's planned clinical development activities for ALKS 1140. The company cautions 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 performance and 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 ALKS 1140 could be shown to be ineffective or unsafe; potential changes in the cost, scope and duration of the ALKS 1140 development program; whether preclinical results for ALKS 1140 will be predictive of results of clinical studies or real-world results; unanticipated impacts of the COVID-19 pandemic on the company's operations; 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.

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