Alkermes to Present Data on ALKS 5461 at Upcoming American Society of Clinical Psychopharmacology Annual Meeting

May 24, 2016

— Company to Host Webcast Presentation and Conference Call on Wednesday, June 1 —

— Management Will Discuss Data and Study Design Details From FORWARD-3 and FORWARD-4, Two Phase 3 Studies of ALKS 5461 for the Treatment of Major Depressive Disorder —

DUBLIN--(BUSINESS WIRE)--May 24, 2016-- Alkermes plc (NASDAQ: ALKS) today announced that data and study design details from FORWARD-3 and FORWARD-4, two phase 3 studies of ALKS 5461 for the adjunctive treatment of major depressive disorder (MDD), will be presented at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting in Scottsdale, Ariz. Management will also host a webcast presentation on June 1, 2016 to discuss the data from FORWARD-3 and FORWARD-4, topline results of which were announced in January 2016. ALKS 5461 is a once-daily, oral investigational medicine with a novel mechanism of action for the adjunctive treatment of MDD in patients who have an inadequate response to standard therapies for clinical depression.

At the ASCP annual meeting, Alkermes will also present posters on two medicines for the treatment of schizophrenia: ALKS 3831, an investigational, novel, oral atypical antipsychotic drug candidate designed to be a broad-spectrum treatment for schizophrenia, and aripiprazole lauroxil, an injectable atypical antipsychotic with approved once-monthly and six-week dosing options. Aripiprazole lauroxil is marketed by Alkermes as ARISTADA® and is approved in the U.S. for the treatment of schizophrenia.

Alkermes presentations at ASCP will include:

ALKS 5461

- Poster #26, “Evaluation of the Efficacy and Safety of ALKS 5461 as Adjunctive Therapy in MDD: Results of FORWARD-3 and FORWARD-4 Studies,” will be available during Poster Session II, Thursday, June 2, 2016, 12:00 p.m. – 2:00 p.m. MST.
- Oral presentation “Characterization of Agonist-Antagonist Opioid Modulation with ALKS 5461 in Major Depression,” will be presented during the Shared Pharmacological Targets for Substance Use and Other Psychiatric Disorders panel on Friday, June 3, 2016, 8:30 a.m. – 10:00 a.m. MST.

ALKS 3831

- Poster #60, “A Phase 2 Efficacy, Safety and Tolerability Study of ALKS 3831 in Schizophrenia With Alcohol Use Disorder,” will describe the design and preliminary patient characteristics of an ongoing study evaluating ALKS 3831 in the treatment of patients with schizophrenia and alcohol use disorder, and will be available during Poster Session II, Thursday, June 2, 2016, 12:00 p.m. – 2:00 p.m. MST.

ARISTADA

- Poster #49, “Symptom Stability in a 52-Week Schizophrenia Extension Study of Treatment With Long-Acting Injectable Aripiprazole Lauroxil,” will be available during Poster Session I, Wednesday, June 1, 2016, 11:15 a.m. – 1:00 p.m. MST.
- Poster #51, “Long-Term Safety and Durability of Effect of Aripiprazole Lauroxil in a One-Year Schizophrenia Extension Study,” will be available during Poster Session II, Thursday, June 2, 2016, 12:00 p.m. – 2:00 p.m. MST.
- Poster #55, “Aripiprazole Lauroxil Pharmacokinetics: Application of Modeling and Simulation for Dosing Considerations of a Long-Acting Injectable Antipsychotic in Persons With Schizophrenia,” will be available during Poster Session II, Thursday, June 2, 2016, 12:00 p.m. – 2:00 p.m. MST.

Further details on the ASCP conference are available at: http://ascpmeeting.org/.

Webcast Presentation and Conference Call
Alkermes will host a webcast presentation with accompanying slides on Wednesday, June 1, 2016, at 8:30 a.m. EDT (1:30 p.m. BST), to discuss data and study design details from the FORWARD-3 and FORWARD-4 studies of ALKS 5461 for the treatment of MDD. The webcast player may be accessed on the Investors section of Alkermes’ website at www.alkermes.com. To participate in the question and answer session, please also dial-in to the conference call which may be accessed by dialing +1 888 424 8151 for U.S. callers and +1 847 585 4422 for international callers. The conference call ID number is 6037988. The webcast presentation will be archived on the Investors section of the Alkermes website for at least 90 days.

About ALKS 5461
ALKS 5461 is a proprietary, oral investigational medicine that acts as a balanced neuromodulator in the brain and represents a novel mechanism of action for treating MDD. ALKS 5461 consists of samidorphan and buprenorphine, and is designed to rebalance brain function that is dysregulated in the state of depression. In October 2013, the FDA granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with an

inadequate response to standard antidepressant therapies.

About ALKS 3831
ALKS 3831 is a proprietary, investigational medicine designed as a broad-spectrum antipsychotic for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan, a novel, new molecular entity co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet.

About ARISTADA®
ARISTADA is an injectable atypical antipsychotic with one-month and six-week dosing options for the treatment of schizophrenia. ARISTADA is administered by a healthcare professional. Once in the body, ARISTADA converts to aripiprazole. ARISTADA was approved by the FDA in October 2015.

INDICATION and IMPORTANT SAFETY INFORMATION for ARISTADA® (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use

INDICATION

ARISTADA is indicated for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA is not approved for the treatment of patients with dementia-related psychosis.

Contraindication: Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Cerebrovascular Adverse Reactions, Including Stroke: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, have been reported in placebo-controlled trials of elderly patients with dementia-related psychosis treated with risperidone, aripiprazole, and olanzapine. ARISTADA is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including ARISTADA. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with oral aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension which can be associated with dizziness, lightheadedness and tachycardia. Monitor heart rate and blood pressure, and warn patients with known cardiovascular or cerebrovascular disease and risk of dehydration and syncope.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis have been reported. Patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) and history of drug-induced leukopenia/neutropenia should have frequent complete blood count (CBC) during the first few months of receiving ARISTADA. Consider discontinuation of ARISTADA at the first sign of a clinically significant decline in WBC count in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue ARISTADA in patients with severe neutropenia (absolute neutrophil count <1000/mm^3) and follow their WBC until recovery.

Seizures: ARISTADA should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: ARISTADA may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain ARISTADA does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use; use caution in patients at risk for aspiration pneumonia.

Concomitant Medication: Decreasing the ARISTADA dosage is recommended in patients taking strong CYP3A4 inhibitors and/or strong CYP2D6 inhibitors for longer than 2 weeks. Increasing the ARISTADA dosage is recommended in patients taking CYP3A4 inducers for longer than 2 weeks. No ARISTADA dosage changes are recommended for patients taking CYP450 modulators for less than 2 weeks.

Most Commonly Observed Adverse Reaction: The most common adverse reaction (≥5% incidence and at least twice the rate of placebo in patients treated with ARISTADA) was akathisia.

Injection-Site Reactions: Injection-site reactions were reported by 4%, 5%, and 2% of patients treated with 441 mg ARISTADA, 882 mg ARISTADA, and placebo, respectively. Most of these were injection-site pain and associated with the first injection and decreased with each subsequent injection. Other injection-site reactions (induration, swelling, and redness) occurred at less than 1%.

Dystonia: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first days of treatment and at low doses.

Pregnancy/Nursing: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare provider of a known or suspected pregnancy. Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ARISTADA during pregnancy. Aripiprazole is present in human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for ARISTADA and any potential adverse effects on the infant from ARISTADA or from the underlying maternal condition.

Please see **FULL PRESCRIBING INFORMATION**, including **Boxed Warning** for ARISTADA.

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.

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