Alkermes to Present Data on Schizophrenia Portfolio at Upcoming Schizophrenia International Research Society Conference

March 28, 2016

— Results From Positive Phase 2 Study of ALKS 3831 for the Treatment of Schizophrenia to be Presented —

— Long-Term Clinical Data on ARISTADA® for the Treatment of Schizophrenia Will Also be Highlighted —

DUBLIN--(BUSINESS WIRE)--Mar. 28, 2016-- Alkermes plc (NASDAQ:ALKS) today announced that data from Alkermes' schizophrenia portfolio will be featured at the 5th Biennial Schizophrenia International Research Society (SIRS) Conference to be held in Florence, Italy on April 2-6, 2016. In addition to positive data from a phase 2 study of ALKS 3831, the company's investigational, novel, oral atypical antipsychotic drug candidate designed to be a broad-spectrum treatment for schizophrenia, the company will present the designs of ongoing clinical studies of ALKS 3831, including the phase 3 pivotal studies. Additionally, data on the long-term clinical benefits of aripiprazole lauroxil, an extended-release injectable suspension, will be presented. Aripiprazole lauroxil is marketed by Alkermes as ARISTADA® and is approved in the U.S. for the treatment of schizophrenia.

Alkermes presentations at SIRS include:

ALKS 3831

- Poster #M63, "A Phase 3 Study to Determine the Antipsychotic Efficacy and Safety of ALKS 3831 in Adult Subjects With Acute Exacerbation of Schizophrenia," will describe the pivotal study design for ALKS 3831 during Poster Session II at the Cavaniglia Pavilion on Monday, April 4, 2016, 11:00 a.m. – 1:00 p.m. CEST.
- Poster #M64, "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 during Poster Session II at the Cavaniglia Pavilion on Monday, April 4, 2016, 11:00 a.m. – 1:00 p.m. CEST.
- Poster #T63, "A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults With Schizophrenia," will describe the pivotal study design for ALKS 3831 during Poster Session III at the Cavaniglia Pavilion on Tuesday, April 5, 2016, 11:00 a.m. – 1:00 p.m. CEST.
- Poster #T62, "ALKS 3831 Demonstrated Equivalent Antipsychotic Efficacy While Addressing Weight Gain: Results from a Phase 2, Randomized, Olanzapine-Controlled Study," will be available during Poster Session III at the Cavaniglia Pavilion on Tuesday, April 5, 2016, 11:00 a.m. – 1:00 p.m. CEST.

ARISTADA

- Poster #M61, "Stability in a 52-Week Schizophrenia Extension Study of Treatment With Long-Acting Injectable Aripiprazole Lauroxil," will be available during Poster Session II at the Cavaniglia Pavilion on Monday, April 4, 2016, 11:00 a.m. – 1:00 p.m. CEST.
- Poster #T59, "Long-Term Safety and Durability of Effect of Aripiprazole Lauroxil in a One-Year Schizophrenia Extension Study," will be available during Poster Session III at the Cavaniglia Pavilion on Tuesday, April 5, 2016, 11:00 a.m. – 1:00 p.m. CEST.

Complete abstracts and further details on the SIRS conference are available at: https://sirs.societyconference.com/conf/#sessions/conf10002.

About Schizophrenia

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.8 million American adults have schizophrenia,[1, 2] with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, which is one of the most serious types of mental illness.

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 plc

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.

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 of, and clinical development plans for, ALKS 3831 and the potential therapeutic and commercial value of ARISTADA for the treatment of schizophrenia. 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 clinical results for ALKS 3831 will be predictive of future clinical study results; whether ALKS 3831 could be shown to be unsafe or ineffective; whether future clinical trials for ALKS 3831 will be initiated or completed on time or at all; and those risks and uncertainties described under the heading "Risk Factors" and elsewhere in the Alkermes plc Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2015, and in other subsequent filings made by the company with the Securities and Exchange Commission ("SEC"), which are available on the SEC's website at 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.

[1] U.S. Census.

[2] National Institute of Mental Health. *Schizophrenia*. Accessed on March 25, 2016 from http://www.nimh.nih.gov/health/statistics/prevalence/schizophrenia.shtml.

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