Alkermes Highlights Presentations From Across Neuroscience Portfolio at Key Fall 2024 Scientific Conferences

November 7, 2024

– 12 Poster Presentations Showcase Research in Schizophrenia, Bipolar I Disorder and Narcolepsy –

– Results Presented From Real-World Retrospective Study of Healthcare Resource Utilization and Treatment Patterns in Patients With Schizophrenia or Bipolar I Disorder Following Initiation of LYBALVI®(olanzapine and samidorphan) –

DUBLIN, Nov. 7, 2024 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced the presentation of research related to LYBALVI® (olanzapine and samidorphan) and ARISTADA® (aripiprazole lauroxil), the company's commercial products in psychiatry, and ALKS 2680, an investigational medicine in development as a once-daily treatment for narcolepsy and idiopathic hypersomnia, at two scientific conferences this fall. The two meetings—the 3rd Annual Psych Congress (Psych Congress), which took place Oct. 29-Nov. 2, 2024 in Boston, and the 2024 Neuroscience Education Institute (NEI) Congress, taking place Nov. 7-10, 2024 in Colorado Springs, Colorado—represent important opportunities for Alkermes to showcase the breadth and depth of its work in neuroscience.

"The wealth of data being presented at these important medical gatherings underscores the substantive research being conducted at Alkermes to understand the experiences of people taking our commercial and investigational medicines, as well as advance knowledge about the complex disease states in which we work," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "We are excited to share our insights with stakeholders from across the psychiatric and neuroscience communities and engage in valuable scientific exchange to help advance care for patients living with schizophrenia, bipolar I disorder and narcolepsy."

Among the posters, Alkermes presented results from a real-world, retrospective study of healthcare resource utilization (HCRU) and treatment patterns in patients with schizophrenia and patients with bipolar I disorder in the 12 months following initiation of LYBALVI. To be included in the study, patients must have had at least one medical or pharmacy claim for LYBALVI, with the date of such claim serving as the date of treatment initiation. The analysis included claims for 1,287 patients with schizophrenia and 1,004 patients with bipolar I disorder enrolled in commercial, Medicare or Medicaid plans and was designed to assess and compare HCRU in the 12 months before and after initiation of LYBALVI.

Among patients with schizophrenia, the research showed statistically significant reductions ($p<0.001$) in all cause, mental health-related, and disease-related inpatient admissions (25%, 27%, and 24% relative reductions, respectively) and emergency department (ED) visits (13%, 27%, and 22% relative reductions, respectively) following initiation on LYBALVI compared to the 12-month period before LYBALVI initiation. Similar results were observed in patients with bipolar I disorder, with statistically significant reductions ($p<0.001$) in all cause, mental health-related, and disease-related inpatient admissions (34%, 39%, and 42% relative reductions, respectively) and ED visits (16%, 32%, and 29% relative reductions, respectively). Change in the number of outpatient visits, inpatient days and length of inpatient stay was also evaluated. Additional analyses were performed in the subset of patients who stayed on LYBALVI for the entire 12-month period, which included 37% of patients with schizophrenia and 30% of patients with bipolar I disorder.

Limitations of the study included those inherent to administrative claims, including that the insured population studied may not be representative of uninsured populations; claims do not capture disease severity and are subject to data omissions or coding errors; the HCRU reported may not fully capture the effects of longer term LYBALVI use; and a claim for a filled prescription does not indicate medication adherence.

In addition, Alkermes presented multiple posters related to the company's work in narcolepsy, including:

- Safety and efficacy data from the proof-of-concept phase 1b study of ALKS 2680, the company's novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist, in patients with narcolepsy type 1 and narcolepsy type 2; and
- Research from in-depth, qualitative interviews and systematic literature reviews designed to better understand the clinical, economic and humanistic burden associated with narcolepsy.

The full list of Alkermes' presentations by meeting is as follows:

Psych Congress

- Poster #23: Safety and Pharmacodynamic Effects of the Orexin 2 Receptor Agonist ALKS 2680 in Patients With Narcolepsy Type 1: A First-in-Human Phase 1 Study
- Poster #125: The Burden of Living With Narcolepsy: Patient Perspectives From In-Depth Qualitative Interviews
- Poster #126: Clinical, Economic, and Humanistic Burden Associated With Narcolepsy: Results From a Systematic Literature Review
- Poster #170: The Orexin 2 Receptor Agonist ALKS 2680 in Patients With Narcolepsy Type 2: An Initial Proof of Concept Phase 1b Study
- Poster #40: Long-Term Safety and Efficacy of Olanzapine/Samidorphan: Results of a 4-Year Open-Label Study
- Poster #62: Healthcare Resource Utilization 12 Months Following Initiation of Olanzapine/Samidorphan: Real-World

Assessment of Patients With Bipolar I Disorder
- Poster #63: Healthcare Resource Utilization 12 Months Following Initiation of Olanzapine/Samidorphan: Real-World Assessment of Patients With Schizophrenia
- Poster #118: Study Retention Rates in the OLZ/SAM Phase III Clinical Program
- Poster #119: Treatment Effects of Olanzapine/Samidorphan on Negative Symptoms in Patients With Schizophrenia: A Post Hoc Analysis
- Poster #69: Baseline Severity of Illness and Response to Treatment With Aripiprazole Lauroxil Every 2 Months: A Post Hoc Analysis of Phase 3 ALPINE Clinical Trial Data
- Poster #70: Treatment Patterns and Healthcare Resource Utilization of Patients With Schizophrenia Prescribed Aripiprazole Lauroxil Versus Oral Aripiprazole: A Retrospective Claims-Based Study
- Poster #100: Treatment Patterns and Healthcare Resource Utilization Following Initiation of Aripiprazole Lauroxil Using a 1-Day Initiation Regimen

NEI Congress

- Poster 73: The Burden of Living With Narcolepsy: Patient Perspectives from In-Depth Qualitative Interviews
- Poster 74: Clinical, Economic, and Humanistic Burden Associated With Narcolepsy: Results From a Systematic Literature Review
- Poster 23: Long-Term Safety and Efficacy of Olanzapine/Samidorphan: Results of a 4-Year Open-Label Study
- Poster 39: Healthcare Resource Utilization 12 Months Following Initiation of Olanzapine/Samidorphan: Real-World Assessment of Patients With Schizophrenia
- Poster 40: Healthcare Resource Utilization 12 Months Following Initiation of Olanzapine/Samidorphan: Real-World Assessment of Patients With Bipolar I Disorder
- Poster 42: Baseline Severity of Illness and Response to Treatment With Aripiprazole Lauroxil Every 2 Months: A Post Hoc Analysis of Phase 3 ALPINE Clinical Trial Data
- Poster 61: Treatment Patterns and Healthcare Resource Utilization Following Initiation of Aripiprazole Lauroxil Using a 1-Day Initiation Regimen
- Poster 62: Treatment Patterns and Healthcare Resource Utilization of Patients With Schizophrenia Prescribed Aripiprazole Lauroxil Versus Oral Aripiprazole: A Retrospective Claims-Based Study

About LYBALVI® (olanzapine and samidorphan)

LYBALVI® (olanzapine and samidorphan) is a once-daily, oral atypical antipsychotic drug approved in the U.S. for the treatment of adults with schizophrenia and for the treatment of adults with bipolar I disorder, as a maintenance monotherapy or for the acute treatment of manic or mixed episodes, as monotherapy or an adjunct to lithium or valproate. LYBALVI is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, in a single bilayer tablet. LYBALVI is available in fixed dosage strengths composed of 10 mg of samidorphan and 5 mg, 10 mg, 15 mg or 20 mg of olanzapine.

IMPORTANT SAFETY INFORMATION for LYBALVI® (olanzapine and samidorphan)

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

Contraindications: LYBALVI is contraindicated in patients who are using opioids or are undergoing acute opioid withdrawal. If LYBALVI is administered with lithium or valproate, refer to the lithium or valproate Prescribing Information for the contraindications for these products.

Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis, including stroke, transient ischemia attack, and fatalities. See Boxed Warning.

Precipitation of Severe Opioid Withdrawal in Patients who are Physiologically Dependent on Opioids: LYBALVI can precipitate opioid withdrawal in patients who are dependent on opioids, which can lead to an opioid withdrawal syndrome, sometimes requiring hospitalization. LYBALVI is contraindicated in patients who are using opioids or undergoing acute opioid withdrawal. Prior to initiating LYBALVI, there should be at least a 7-day opioid-free interval from last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids. Explain the risks associated with precipitated withdrawal and the importance of giving an accurate account of last opioid use to patients and caregivers.

Vulnerability to Life-Threatening Opioid Overdose: Attempting to overcome opioid blockade with high or repeated doses of exogenous opioids could lead to life-threatening or fatal opioid intoxication, particularly if LYBALVI therapy is interrupted or discontinued, subjecting the patient to high levels of unopposed opioid agonist as the samidorphan blockade wanes. Inform patients of the potential consequences of trying to overcome the opioid blockade and the serious risks of taking opioids concurrently with LYBALVI or while transitioning off LYBALVI. In emergency situations, if a LYBALVI-treated patient requires opioid treatment as part of anesthesia or analgesia, discontinue LYBALVI. Opioids should be administered by properly trained individual(s) and patient should be continuously monitored in a setting equipped and staffed for cardiopulmonary resuscitation. Patients with a history of chronic opioid use prior to treatment with LYBALVI may have decreased opioid tolerance if LYBALVI therapy is interrupted or discontinued. Advise patients that this decreased tolerance may increase the risk of opioid overdose if opioids are resumed at the previously tolerated dosage.

Neuroleptic Malignant Syndrome, a potentially fatal reaction. Signs and symptoms include hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation, intensive symptomatic treatment, and close monitoring.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), a potentially fatal condition reported with exposure to olanzapine, a component of LYBALVI. Symptoms include a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. Discontinue if DRESS is suspected.

Metabolic Changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Any patient treated with LYBALVI should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required anti-diabetic treatment despite discontinuation of the suspect drug. Measure weight and assess fasting glucose and lipids when initiating LYBALVI and monitor periodically.

Tardive Dyskinesia (TD): Risk of developing TD (a syndrome of potentially irreversible, involuntary, dyskinetic movements) and the likelihood it will become irreversible increases with the duration of treatment and the cumulative dose. The syndrome can develop after a relatively brief treatment period, even at low doses, or after discontinuation. Given these considerations, LYBALVI should be prescribed in a manner that is most likely to reduce the risk of tardive dyskinesia. If signs and symptoms of TD appear, drug discontinuation should be considered.

Orthostatic Hypotension and Syncope: Monitor orthostatic vital signs in patients who are vulnerable to hypotension, patients with known cardiovascular disease, and patients with cerebrovascular disease.

Falls: LYBALVI may cause somnolence, postural hypotension, and motor and sensory instability, which may lead to falls, and consequently, fractures or other injuries. Assess patients for risk when using LYBALVI.

Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases): Perform complete blood counts in patients with a history of a clinically significant low white blood cell (WBC) count or history of leukopenia or neutropenia. Discontinue LYBALVI if clinically significant decline in WBC occurs in the absence of other causative factors.

Dysphagia: Use LYBALVI with caution in patients at risk for aspiration.

Seizures: Use LYBALVI with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: Because LYBALVI may cause somnolence, and may impair judgment, thinking, or motor skills, caution patients about operating hazardous machinery, including motor vehicles, until they are certain that LYBALVI does not affect them adversely.

Body Temperature Dysregulation: Use LYBALVI with caution in patients who may experience conditions that increase core body temperature (e.g., strenuous exercise, extreme heat, dehydration, or concomitant use with anticholinergics).

Anticholinergic (Antimuscarinic) Effects: Olanzapine, a component of LYBALVI, was associated with constipation, dry mouth, and tachycardia. Use LYBALVI with caution with other anticholinergic medications and in patients with urinary retention, prostatic hypertrophy, constipation, paralytic ileus or related conditions. In postmarketing experience, the risk for severe adverse reactions (including fatalities) was increased with concomitant use of anticholinergic medications.

Hyperprolactinemia: LYBALVI elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.

Risks Associated with Combination Treatment with Lithium or Valproate: If LYBALVI is administered with lithium or valproate, refer to the lithium or valproate Prescribing Information for a description of the risks for these products.

Interference with Laboratory Tests for Opioid Detection: LYBALVI may cause false positive results with urinary immunoassay methods for detecting opioids. Use an alternative analytical technique (e.g., chromatographic methods) to confirm positive opioid urine drug screen results.

Most Common Adverse Reactions observed in clinical trials were:

- *Schizophrenia (LYBALVI):* weight increased, somnolence, dry mouth, and headache
- *Bipolar I Disorder, Manic or Mixed Episodes (olanzapine):* somnolence, dry mouth, dizziness, asthenia, constipation, dyspepsia, increased appetite, and tremor
- *Bipolar I Disorder, Manic or Mixed Episodes, adjunct to lithium or valproate (olanzapine):* dry mouth, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, paresthesia

Concomitant Medication: LYBALVI is contraindicated in patients who are using opioids or undergoing acute opioid withdrawal. Concomitant use of LYBALVI is not recommended with strong CYP3A4 inducers, levodopa and dopamine agonists. Reduce dosage of LYBALVI when using with strong CYP1A2 inhibitors. Increase dosage of LYBALVI with CYP1A2 inducers. Use caution with diazepam, alcohol, other CNS acting drugs, or in patients receiving anticholinergic (antimuscarinic) medications. Monitor blood pressure and reduce dosage of antihypertensive drug in accordance with its approved product labeling.

Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with LYBALVI. Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to LYBALVI during pregnancy.

Renal Impairment: LYBALVI is not recommended for patients with end-stage renal disease (eGFR of <15 mL/minute/1.73 m^2).

Please click here for full Prescribing Information, including Boxed Warning, for LYBALVI.

About ARISTADA® (aripiprazole lauroxil) Extended-Release Injectable Suspension, for Intramuscular Use

ARISTADA is an injectable atypical antipsychotic approved in four dose strengths and three dosing durations for the treatment of schizophrenia in adults (441 mg, 662 mg or 882 mg monthly, 882 mg once every six weeks and 1064 mg once every two months). Once in the body, ARISTADA

converts to aripiprazole.

About ARISTADA INITIO® (aripiprazole lauroxil) Extended-Release Injectable Suspension, for Intramuscular Use

ARISTADA INITIO, in combination with a single 30 mg dose of oral aripiprazole, is indicated for the initiation of ARISTADA when used for the treatment of schizophrenia in adults. The first ARISTADA dose may be administered on the same day as the ARISTADA INITIO regimen or up to 10 days thereafter.

IMPORTANT SAFETY INFORMATION for ARISTADA INITIO® and ARISTADA®

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 INITIO and ARISTADA are 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 INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

Potential for Dosing and Medication Errors: Medication errors, including substitution and dispensing errors, between ARISTADA INITIO and ARISTADA could occur. ARISTADA INITIO is intended for single administration in contrast to ARISTADA which is administered monthly, every 6 weeks, or every 8 weeks. Do not substitute ARISTADA INITIO for ARISTADA because of differing pharmacokinetic profiles.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex may occur with administration of antipsychotic drugs, including ARISTADA INITIO and 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 antipsychotics should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. TD 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.

Pathological Gambling and Other Compulsive Behaviors: Compulsive or uncontrollable urges to gamble have been reported with use of aripiprazole. Other compulsive urges less frequently reported include sexual urges, shopping, binge eating and other impulsive or compulsive behaviors which may result in harm for the patient and others if not recognized. Closely monitor patients and consider dose reduction or stopping aripiprazole if a patient develops such urges.

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.

Falls: Antipsychotics including ARISTADA INITIO and ARISTADA may cause somnolence, postural hypotension or motor and sensory instability which may lead to falls and subsequent injury. Upon initiating treatment and recurrently, complete fall risk assessments as appropriate.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC)/absolute neutrophil count or history of drug-induced leukopenia/neutropenia. Discontinue ARISTADA INITIO and/or ARISTADA at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

Seizures: Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: ARISTADA INITIO and ARISTADA may impair judgment, thinking, or motor skills. Patients should be

cautioned about operating hazardous machinery, including automobiles, until they are certain therapy with ARISTADA INITIO and/or 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: ARISTADA INITIO is only available at a single strength as a single-dose pre-filled syringe, so dosage adjustments are not possible. Avoid use in patients who are known CYP2D6 poor metabolizers or taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers, antihypertensive drugs or benzodiazepines.

Depending on the ARISTADA dose, adjustments may be recommended if patients are 1) known as CYP2D6 poor metabolizers and/or 2) taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers for greater than 2 weeks. Avoid use of ARISTADA 662 mg, 882 mg, or 1064 mg for patients taking both strong CYP3A4 inhibitors and strong CYP2D6 inhibitors. (See Table 4 in the ARISTADA full Prescribing Information.)

Commonly Observed Adverse Reactions: In pharmacokinetic studies the safety profile of ARISTADA INITIO was generally consistent with that observed for ARISTADA**.** The most common adverse reaction (≥5% incidence and at least twice the rate of placebo reported by patients treated with ARISTADA 441 mg and 882 mg monthly) was akathisia.

Injection-Site Reactions: In pharmacokinetic studies evaluating ARISTADA INITIO, the incidences of injection site reactions with ARISTADA INITIO were similar to the incidence observed with ARISTADA. Injection-site reactions were reported by 4%, 5%, and 2% of patients treated with 441 mg ARISTADA (monthly), 882 mg ARISTADA (monthly), 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 INITIO and/or 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 INITIO and/or ARISTADA and any potential adverse effects on the infant from ARISTADA INITIO and/or ARISTADA or from the underlying maternal condition.

Please see full Prescribing Information, including Boxed Warning, for ARISTADA INITIO, and full Prescribing Information, including Boxed Warning, for ARISTADA.

About ALKS 2680

ALKS 2680 is a novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in development as a once-daily treatment for narcolepsy type 1 (NT1), narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH). Orexin, a neuropeptide produced in the lateral hypothalamus, is considered to be the master regulator of wakefulness due to its activation of multiple, downstream wake-promoting pathways that project widely throughout the brain.[1] Targeting the orexin system may address excessive daytime sleepiness across hypersomnolence disorders, whether or not deficient orexin signaling is the underlying cause of disease.[2] Once-daily oral administration of ALKS 2680 was previously evaluated in a phase 1 study in healthy volunteers and patients with NT1, NT2 and IH, and is currently being evaluated in the phase 2 Vibrance-1 and Vibrance-2 studies in patients with NT1 and NT2, respectively.

About Alkermes plc

Alkermes plc is a global biopharmaceutical company that seeks to develop innovative medicines in the field of neuroscience. The company has a portfolio of proprietary commercial products for the treatment of alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of clinical and preclinical candidates in development for neurological disorders, including narcolepsy and idiopathic hypersomnia. Headquartered in Ireland, Alkermes also has a corporate office and research and development center in Massachusetts and a manufacturing facility in Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

[1] Buysse, D. Diagnosis and assessment of sleep and circadian rhythm disorders. *Journal of Psychiatric Practice*. 2005; 11(2):102-115

[2] Ten-Blanco M, Flores A, Cristino L, Pereda-Perez I. Targeting the orexin/hypocretin system for the treatment of neuropsychiatric and neurodegenerative diseases: From animal to clinical studies. Frontiers in Neuroendocrinology. 2023; 69(101066). https://www.sciencedirect.com/science/article/pii/S0091302223000146

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