



## Alkermes and Collaborators to Present Data from Three Ongoing Clinical Development Programs at Two Major Medical Meetings

December 3, 2012

— *Pharmacokinetic Data Supporting Phase 3 Development of ALKS 9070, a Long-Acting Injectable Antipsychotic, to be Presented at the Annual Meeting of the American College of Neuropsychopharmacology (ACNP)* —

— *Phase 1/2 Data of Novel Depression Drug Candidate, ALKS 5461, Will Also be Highlighted at ACNP* —

— *Clinical and Pharmacoeconomic Analyses of VIVITRO<sup>®</sup> in the Treatment of Alcohol and Opioid Dependence to be Presented at the American Academy of Addiction Psychiatry Annual Meeting* —

DUBLIN--(BUSINESS WIRE)--Dec. 3, 2012-- [Alkermes plc](#) (NASDAQ: ALKS) today announced that data on three of the company's clinical programs are scheduled to be presented at two upcoming major medical meetings this week. At the Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in Hollywood, Fla., Dec. 2-6, 2012, Alkermes will present pharmacokinetic data on ALKS 9070, a new chemical entity currently in phase 3 development for the treatment of schizophrenia. Results will be shown from a clinical trial supporting the once-monthly dosing regimen for this novel injectable agent. Also at that meeting, positive results will be presented from a phase 1/2 study of ALKS 5461, Alkermes' novel drug candidate for major depressive disorder (MDD), in patients who have an inadequate response to standard therapies for clinical depression. Data relating to the potential use of ALKS 5461 in the treatment of cocaine dependence will also be presented.

At the American Academy of Addiction Psychiatry (AAAP) Annual Meeting in Aventura, Fla., Dec. 6-9, 2012, new data on the clinical and pharmacoeconomic benefits of naltrexone for extended-release injectable suspension (XR-NTX) will be presented. XR-NTX is marketed by Alkermes as VIVITROL<sup>®</sup> and is approved in the U.S. for the treatment of alcohol dependence and the prevention of relapse to opioid dependence following opioid detoxification.

Key presentations for these two medical meetings include:

### ACNP

Monday, Dec. 3, 2012, at 3:00 p.m. EST

The oral presentation, "New Clinical Research in Opioid Modulation Indicates Novel Utility in Treating Resistant Depression" will be given by Elliot Ehrlich, M.D., Alkermes, Inc., during a mini-panel session entitled, "Renaissance in Opioid Biology: From Preclinical Concepts to Clinical Practice."

Wednesday, Dec. 5, 2012, at 5:30 p.m. EST

Poster 18: "ALKS 5461, a Novel Opioid Receptor Modulator, Reduces the Subjective Effects of Cocaine and was Safe and Well Tolerated During Concurrent Cocaine Administration" will be presented by Ryan Turncliff, Ph.D., Alkermes, Inc.

Poster 173: "ALKS 5461, a Novel Opioid Receptor Modulator, Normalizes Human EEG Responses in an Auditory Oddball Task After Cocaine Administration as Indicated by a Novel Brain Network Activation Analysis" will be presented by Edward Sellers, M.D., Ph.D., President and Principal, DL Global Partners Inc.

Poster 174: "Pharmacokinetic Modeling of ALKS 9070 (ALKS 9072), a Novel Once-Monthly Prodrug of Aripiprazole" will be presented by Ryan Turncliff, Ph.D., Alkermes, Inc.

Further details on the ACNP Annual Meeting are available at: [www.acnp.org/annualmeeting](http://www.acnp.org/annualmeeting).

### AAAP

Saturday, Dec. 8, 2012, at 5:00 p.m. EST

"Medication and Non-Medication Treatment of Alcohol Dependence: A NNT (Number Needed to Treat) Analysis" will be presented by David Gastfriend, M.D., Alkermes, Inc.

"Extended-Release Naltrexone (XR-NTX) in Inpatient Rehab Post-Detox: Retention, Readmission, Clinical Experience and Impact on Managed Care" will be presented by Kathleen Brady, M.D., Ph.D., Professor and Director, Clinical Neuroscience Division at the Medical University of South Carolina.

"Cost-Effectiveness of Treatment with Extended-Release Naltrexone: A Meta-Analysis Across Five Studies" will be presented by David Gastfriend, M.D., Alkermes, Inc.

"Extended-Release Injectable Naltrexone (XR-NTX) for Opioid Dependence: Efficacy in Depressed Patients and Other Clinically Relevant Subpopulations" will be presented by Edward Nunes, M.D., Professor of Clinical Psychiatry at Columbia University Medical Center.

Further details on the AAAP Annual Meeting are available at: [www.aaap.org/meetings-and-events/2012-annual-meeting](http://www.aaap.org/meetings-and-events/2012-annual-meeting).

### About ALKS 9070 and LinkeRx<sup>®</sup>

LinkeRx is a novel, proprietary technology platform developed by Alkermes that enables the creation of injectable extended-release atypical antipsychotics and other central nervous system (CNS) therapies. ALKS 9070, which leverages the LinkeRx technology, is a once-monthly, injectable atypical antipsychotic in development for the treatment of schizophrenia. Once in the body, ALKS 9070 converts to aripiprazole. Aripiprazole is commercially available under the name ABILIFY<sup>®</sup> for the treatment of a number of CNS disorders.

### About ALKS 5461

ALKS 5461 is the combination of ALKS 33 and buprenorphine and is designed to be a non-addictive opioid modulator. ALKS 33 is an oral opioid modulator that builds on Alkermes' scientific expertise in opioid biology and pharmacology, as well as the company's clinical and commercial knowledge in the field of addiction and CNS disorders. ALKS 5461 is in clinical development for the treatment of MDD in patients who have an inadequate response to standard therapies for clinical depression, as well as for the treatment of cocaine dependence, which is being funded through a grant from the National Institute on Drug Abuse (NIDA).

#### **About VIVITROL**

**VIVITROL** (naltrexone for extended-release injectable suspension) 380 mg/vial is the first and only once-monthly, extended-release injectable medication for the treatment of alcohol dependence and opioid dependence. The proprietary Medisorb<sup>®</sup> drug delivery technology in VIVITROL enables the medication to be gradually released into the body at a controlled rate over a one-month time period. Treatment with VIVITROL should be part of a comprehensive treatment program that includes psychosocial support. VIVITROL has been studied in more than 1,000 patients and has been used to treat more than 45,000 people for alcohol and opioid dependence in the U.S. The VIVITROL clinical development program was funded in part with a Small Business Innovation Research Program grant from NIDA. For a copy of the VIVITROL full prescribing information, please visit [www.vivitrol.com](http://www.vivitrol.com) or call 1-800-VIVITROL (1-800-848-4876). Please see below for important safety information, including boxed warning.

#### **Important Safety Information for VIVITROL<sup>®</sup> (naltrexone for extended-release injectable suspension) 380 mg/vial.**

##### **WARNING: HEPATOTOXICITY**

**Naltrexone has the capacity to cause hepatocellular injury when given in excessive doses.**

**Naltrexone is contraindicated in acute hepatitis or liver failure, and its use in patients with active liver disease must be carefully considered in light of its hepatotoxic effects.**

**The margin of separation between the apparently safe dose of naltrexone and the dose causing hepatic injury appears to be only five-fold or less. VIVITROL does not appear to be a hepatotoxin at the recommended doses.**

**Patients should be warned of the risk of hepatic injury and advised to seek medical attention if they experience symptoms of acute hepatitis. Use of VIVITROL should be discontinued in the event of symptoms and/or signs of acute hepatitis.**

##### **CONTRAINDICATIONS**

VIVITROL is contraindicated in patients with acute hepatitis or liver failure, patients receiving opioid analgesics, patients with current physiologic opioid dependence, patients in acute opioid withdrawal, any individual who has failed the naloxone challenge test or has a positive urine screen for opioids, and in patients who have previously exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose or any other components of the diluent.

##### **WARNINGS/PRECAUTIONS**

- **Injection Site Reactions:** VIVITROL is administered as an intramuscular (IM) gluteal injection. Inadvertent subcutaneous injection of VIVITROL may increase the likelihood of severe injection site reactions. VIVITROL must be injected using one of the customized needles provided in the carton. Because needle length may not be adequate due to body habitus, each patient should be assessed prior to each injection to assure that needle length is adequate for IM administration. VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising or pruritus; however, in some cases injection site reactions may be very severe. Injection site reactions not improving may require prompt medical attention, including in some cases surgical intervention.
- **Eosinophilic Pneumonia:** VIVITROL patients should be warned of the risk of eosinophilic pneumonia, and advised to seek medical attention should they develop symptoms of pneumonia.
- **Hypersensitivity Reactions Including Anaphylaxis:** Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.
- **Unintended Precipitation of Opioid Withdrawal:** Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, must be opioid-free for a minimum of 7-10 days before starting VIVITROL treatment.
- **Opioid Overdose at the End of a Dosing Interval, After Missing a Dose and Following an Attempt to Overcome Opioid Blockade:** Use of lower doses of opioids after VIVITROL treatment is discontinued, at the end of a dosing interval, or after missing a dose could result in life-threatening opioid intoxication. Any attempt by a patient to overcome the blockade produced by VIVITROL by taking opioids is very dangerous and may lead to fatal overdose.
- **Depression and Suicidality:** VIVITROL patients should be monitored for the development of depression or suicidal thinking.
- **Intramuscular Injections:** VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder.
- **When Reversal of VIVITROL Blockade is Required for Pain Management:** In an emergency situation in patients receiving VIVITROL, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

##### **ADVERSE EVENTS**

The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence include nausea, vomiting, injection site reactions (including induration, pruritus, nodules and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders. The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

##### **About Alkermes plc**

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a

substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and 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 above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These 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 contemplated in these forward-looking statements.

These risks and uncertainties include the risks described in the company's Annual Report on Form 10-K for the year ended March 31, 2012, and in other filings made by the company with the Securities and Exchange Commission ("SEC") and which are available at the SEC's website at [www.sec.gov](http://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 they are made. 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 any forward-looking information contained in this press release.

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Source: Alkermes plc

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