Alkermes CEO Richard Pops Testified at President's Commission on Combating Drug Addiction and the Opioid Crisis

Release Date: Thursday, September 28, 2017

Alkermes CEO Richard Pops joined government, nonprofit, and business organizations at the Third Meeting of the President's Commission on Combating Drug Addiction and the Opioid Crisis to testify in support of the Commission's ongoing effort to discuss innovative solutions to address the opioid crisis.

Central to the meeting's focus on prevention of the diversion of opioids and novel approaches to pain management, Mr. Pops' testimony highlighted the following:

- The opioid epidemic is devastating families and communities across the country, threatening American productivity and the very fabric of many communities.

- All FDA-approved medications have an important role to play in addressing the opioid epidemic. No one medication is right for everyone.

- The importance of patient-centered care. The medication a patient receives should not be based solely on the treatment setting. Healthcare professionals, their patients and caregivers should be made aware of, and able to access, all available FDA-approved treatment options for opioid dependence so that patients receive the treatment that is best for them. In this context, Alkermes supports implementation of the Comprehensive Addiction and Recovery Act.

- The role of VIVITROL® (naltrexone for extended-release injectable suspension), an FDA-approved medicine for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL offers patients, clinicians and the community a treatment option that has no risk of abuse and that is not diverted, traded or sold illicitly on the street.

- Long-acting injectable (LAI) formulations represent an important treatment option for patients. LAI formulations, such as VIVITROL, which are administered by healthcare professionals, allow healthcare professionals, family members and other members of the treatment team to know whether the patient is taking his or her medicine. Yet despite these benefits of LAIs, there are significant barriers to reimbursement and access for patients in need of treatment that must be addressed.

- The importance of developing new medications for the treatment of depression, given the association between untreated and undertreated depression and the concurrent use and abuse of opioids.

VIVITROL represents Alkermes' long-term commitment to this critical and challenging public health issue—but it will take collaboration across the entire addiction community to meaningfully address the opioid crisis. Mr. Pops and Alkermes applaud the efforts of the Opioid Commission, led by Governor Christie, for elevating this issue and bringing people together to address the opioid epidemic across the country.

About VIVITROL®

VIVITROL (naltrexone for extended-release injectable suspension) is a once-monthly medication for the treatment of alcohol dependence as well as for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL is the first and only non-narcotic, non-addictive, once-monthly medication approved for the treatment of opioid dependence. Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support.

IMPORTANT SAFETY INFORMATION

WHAT IS VIVITROL®?

VIVITROL (naltrexone for extended-release injectable suspension) is a prescription injectable medicine used to:

- Treat alcohol dependence. You should stop drinking before starting VIVITROL.
- Prevent relapse to opioid dependence **after** opioid detox. You must stop taking opioids or other opioid-containing medications before starting VIVITROL.

VIVITROL must be used with other alcohol or drug recovery programs such as counseling.

VIVITROL may not work for everyone and has not been studied in children.

DO NOT TAKE VIVITROL IF YOU:

- Are still using or still have any symptoms of physical withdrawal due to dependence on opioid street drugs or opioid-containing medicines.
- Have opioid withdrawal symptoms.
- Are allergic to naltrexone or any of the ingredients in VIVITROL or the liquid used to mix VIVITROL.

See the Medication Guide for more information about opioid withdrawal and the ingredients in VIVITROL and the liquid used to mix it.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT VIVITROL?

VIVITROL can cause serious side effects, including:

RISK OF OPIOID OVERDOSE

Using opioids, even in amounts that you used before VIVITROL treatment, can lead to accidental overdose, serious injury, coma or death. To avoid accidental overdose:

- **Do not** take large amounts of opioids or try to overcome the opioid-blocking effects of VIVITROL.
- Do not use opioids in amounts that you used before VIVITROL treatment. You may even be more sensitive to **lower** amounts of opioids:
    - After detox.
    - When your next VIVITROL dose is due.
    - If you miss a dose of VIVITROL.
    - After you stop VIVITROL treatment.

Get emergency medical help right away if you have trouble breathing; become very drowsy with slowed breathing; have slow, shallow breathing; feel faint, dizzy, confused; or have other unusual symptoms.

SEVERE REACTIONS AT THE INJECTION SITE

VIVITROL may cause severe injection site reactions, including tissue death. Some injection site reactions have required surgery. Call your doctor right away if you notice any of the following at your injection site:

- Intense pain
- The area feels hard
- Swelling
- Lumps
- Blisters
- An open wound
- A dark scab

Tell your doctor about any injection site reaction that concerns you, gets worse overtime or does not get better by two weeks after the injection.

SUDDEN OPIOID WITHDRAWAL

To avoid sudden opioid withdrawal, you must stop taking any opioids or opioid-containing medications, including buprenorphine or methadone, **for at least 7 to 14 days** before starting VIVITROL. If your doctor decides that you don't need to complete detox first, he or she may give you VIVITROL in a medical facility that can treat sudden opioid withdrawal.

Sudden opioid withdrawal can be severe and may require hospitalization.

LIVER DAMAGE OR HEPATITIS

Naltrexone, the active ingredient in VIVITROL, can cause liver damage or hepatitis. Tell your doctor if you have any of the following symptoms of liver problems during VIVITROL treatmen

Stomach area pain lasting more than a few days

- Yellowing of the whites of your eyes
- Dark urine
- Tiredness

OTHER POSSIBLE SIDE EFFECTS

VIVITROL can cause other serious side effects, such as:

- **Depressed mood –** Sometimes this leads to suicide or suicidal thoughts and behavior. Tell those closest to you that you are taking VIVITROL. You or those closest to you should call your doctor right away if you become depressed or have any new or worsening depression symptoms.
- **Allergic pneumonia –** Tell your healthcare provider if you have shortness of breath, wheezing or a cough that doesn't go away.
- **Serious allergic reactions –** Get medical help immediately if you have a skin rash; swelling of your face, eyes, mouth or tongue; trouble breathing or wheezing; chest pain; or are feeling dizzy or faint.

Common side effects of VIVITROL include nausea, tiredness, headache, dizziness, vomiting, decreased appetite, painful joints, and muscle cramps; in addition, common side effects in people taking VIVITROL for opioid dependence also include cold symptoms, trouble sleeping and toothache.

These are not all of the side effects of VIVITROL. For more information, ask your healthcare provider. Tell your doctor right away if you have any side effect that does not go away. See the Medication Guide for more information.

Call your doctor for medical advice about any side effects. You are encouraged to report negative side effects to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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.