January 8, 2018

# Adamas Announces U.S. Commercial Launch of GOCOVRI™ the First and Only FDA-approved Medication for the Treatment of Dyskinesia in Parkinson's Disease Patients

EMERYVILLE, Calif., Jan. 08, 2018 (GLOBE NEWSWIRE) -- Adamas Pharmaceuticals, Inc. (Nasdaq:ADMS) today announced the full commercial launch of its flagship product, GOCOVRI™ (amantadine) extended release capsules, for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. GOCOVRI was approved by the U.S. Food and Drug Administration (FDA) in August 2017, when it was granted seven years of orphan drug exclusivity, and has been available for physician and patient use since October 2017. Today's launch marks the deployment of Adamas' dedicated team of 59 neurology field sales professionals, who are focused on educating the Parkinson's disease community about the benefit/safety profile of GOCOVRI.

"The full commercial launch of GOCOVRI represents an important milestone for Adamas and will significantly expand awareness of GOCOVRI for both physicians and patients," said Gregory T. Went, Ph.D., Founder, Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. "We are pleased with the early interest in GOCOVRI, as at least 100 distinct physicians and other healthcare professionals have already prescribed GOCOVRI to their patients, with access support provided to eligible patients through GOCOVRI Onboard™, our patient services support program."

"The launch of GOCOVRI, which was demonstrated in clinical studies to reduce both dyskinesia and OFF time, gives physicians a new tool for the treatment of Parkinson's disease patients with dyskinesia," said Dr. Rajesh Pahwa, Professor of Neurology and Chief, Parkinson's Disease Center, University of Kansas Medical Center, Kansas City. "I believe GOCOVRI also represents a broad, comprehensive scientific approach to treating Parkinson's disease based on Adamas' focus and understanding of the time-dependent aspects of Parkinson's disease symptoms and the intrinsic role of the glutamate pathway in Parkinson's disease versus the more commonly addressed dopaminergic pathway."

**About Parkinson's Disease and Dyskinesia**
In the United States, there are close to one million people living with Parkinson's disease, a chronic neurodegenerative disorder, and an estimated 150,0000 - 200,000 people recognizing they have dyskinesia. Parkinson's disease is characterized by dopamine deficiency combined with an over-activated glutamate system, which contributes to the symptoms of dyskinesia and OFF time, which is characterized by slowness of movement, rigidity, impaired walking, tremor, and postural instability. Over time, nearly 90 percent of people with Parkinson's disease develop dyskinesia, which occurs throughout the day. Dyskinesia is a consequence of levodopa-based treatment and progression of Parkinson's disease, and is characterized by involuntary and non-rhythmic movements that are purposeless and unpredictable, which often impacts the activities of daily living. Until approval of GOCOVRI, the primary strategy to manage dyskinesia has been to fractionate or lower the levodopa dose, which may reduce dyskinesia in some cases, but because of the reduced levodopa dosing, can lead to increased OFF time in patients.

**About GOCOVRI™**
GOCOVRI (amantadine) extended release capsules is the first and only medicine approved by the FDA for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. GOCOVRI is a high-dose 274 mg amantadine (340 mg amantadine hydrochloride) taken once-daily at bedtime, which delivers consistently high levels of amantadine in the morning and throughout the day. Data from two pivotal, placebo-controlled clinical studies in over 200 patients demonstrated statistically significant reduction in dyskinesia, as well as a secondary benefit in OFF time in patients dosed with GOCOVRI. For more information about GOCOVRI, please see the important safety information below and the U.S. Prescribing Information at www.gocovri.com.

**About GOCOVRI Onboard™**
Adamas is committed to helping people with Parkinson's disease and dyskinesia gain access to GOCOVRI. Adamas has created GOCOVRI Onboard, a patient services program, which facilitates access to, and distribution of the medicine. GOCOVRI Onboard will work with patients, their families and physicians to obtain access to GOCOVRI via reimbursement support, prescription fulfillment and financial assistance. GOCOVRI Onboard is designed to deliver dedicated assistance and financial support to patients in need. For more information, visit www.gocovri.com/patient-support/.

**About Adamas Pharmaceuticals, Inc.**
Adamas uses its deep understanding of time-dependent biology to redefine the treatment experience for patients suffering from chronic neurological diseases. Building upon the commercial launch of GOCOVRI™ (amantadine) extended release capsules (previously ADS-5102), the first and only FDA-approved medicine for the treatment of dyskinesia in patients with

Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications and its advancing pipeline of differentiated investigational programs, which includes ADS-5102 in development for the treatment of multiple sclerosis walking impairment; and ADS-4101, a high-dose, modified-release lacosamide in development for the treatment of partial onset seizures in patients with epilepsy, Adamas' goal is to create and commercialize a new generation of medicines intended to lessen the burden of disease on patients, caregivers and society. Its unique expertise lies in uncovering and mapping the relationship between disease and drug activity to create medicines with therapeutic profiles that match the pattern of disease to drive a highly significant and durable clinical effect. This understanding of time-dependent biological processes informs every innovation, targeting advancement in treatment of chronic neurologic disorders. For more information, please visit www.adamaspharma.com.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**
GOCOVRI™ (amantadine) is contraindicated in patients with creatinine clearance below 15 mL/min/1.73 m2.

**WARNINGS AND PRECAUTIONS**
**Falling Asleep During Activities of Daily Living and Somnolence**: Patients treated with Parkinson's disease medications have reported falling asleep during activities of daily living. If a patient develops daytime sleepiness during activities that require full attention (e.g., driving a motor vehicle, conversations, eating), GOCOVRI should ordinarily be discontinued or the patient should be advised to avoid potentially dangerous activities.
**Suicidality and Depression:** Monitor patients for depression, including suicidal ideation or behavior. Prescribers should consider whether the benefits outweigh the risks of treatment with GOCOVRI in patients with a history of suicidality or depression.
**Hallucinations/Psychotic Behavior:** Patients with a major psychotic disorder should ordinarily not be treated with GOCOVRI because of the risk of exacerbating psychosis. Observe patients for the occurrence of hallucinations throughout treatment, especially at initiation and after dose increases.
**Dizziness and Orthostatic Hypotension:** Monitor patients for dizziness and orthostatic hypotension, especially after starting GOCOVRI or increasing the dose.
**Withdrawal-Emergent Hyperpyrexia and Confusion:** Rapid dose reduction or abrupt discontinuation of GOCOVRI, may cause an increase in the symptoms of Parkinson's disease or cause delirium, agitation, delusions, hallucinations, paranoid reaction, stupor, anxiety, depression, or slurred speech. Avoid sudden discontinuation of GOCOVRI.
**Impulse Control/Compulsive Behaviors:** Patients may experience urges (e.g. gambling, sexual, money spending, binge eating) and the inability to control them. It is important for prescribers to ask patients or their caregivers about the development of new or increased urges. Consider dose reduction or stopping medications.

**ADVERSE REACTIONS**
The most common adverse reactions ( > 10%) were hallucination, dizziness, dry mouth, peripheral edema, constipation, fall, and orthostatic hypotension.

**DRUG INTERACTIONS**
**Other Anticholinergic Drugs:** The dose of GOCOVRI should be reduced if atropine-like effects are observed.
**Drugs Affecting Urinary pH:** The pH of the urine has been reported to influence the excretion rate of amantadine. Monitor for efficacy or adverse reactions under conditions that alter the urine pH.
**Alcohol:** Concomitant use with alcohol is not recommended, as it may increase the potential for CNS effects such as dizziness, confusion, lightheadedness, and orthostatic hypotension.

View the full GOCOVRI Prescribing Information.

**Forward-looking Statements**
Statements contained in this press release regarding matters or events that may occur in the future are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to, statements contained in this press release regarding the expected expanded awareness of GOCOVRI from the commercial launch of GOCOVRI for treatment of levodopa-induced dyskinesia in patients with Parkinson's disease, physician interest in the GOCOVRI, expectations regarding how GOCOVRI Onboard will work, and Adamas' advancing pipeline, including the potential for additional clinical development programs for ADS-5102 including walking impairment in multiple sclerosis, and the advancement of ADS-4101 in clinical development. Words such as "will," "potential," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. For a description of risks and uncertainties that could cause actual results to differ from those expressed in forward-looking statements, including risks relating to Adamas' research, clinical, development and commercial activities relating to GOCOVRI, ADS-5102 and ADS-4101, the regulatory and competitive environment and Adamas' business in general, see Adamas' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 2, 2017. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Adamas undertakes no obligation to update any

forward-looking statement in this press release.

Contacts:

Media:

Kim Kraemer

415-939-9033

kkraemer@waterhousebrands.com

Investors:

Ashleigh Barreto

Director, Corporate Communications & Investor Relations

Adamas Pharmaceuticals, Inc.

510-450-3567

ir@adamaspharma.com


Primary Logo

Source: Adamas Pharmaceuticals, Inc.

News Provided by Acquire Media