



August 24, 2017

Adamas Announces FDA Approval of GOCOVRI™ as First and Only Medication for the Treatment of Dyskinesia in Parkinson's Disease Patients

-- Conference call and webcast scheduled for today at 4:30 pm ET --

EMERYVILLE, Calif., Aug. 24, 2017 (GLOBE NEWSWIRE) -- Adamas Pharmaceuticals, Inc. (Nasdaq:ADMS) today announced that the U.S. Food and Drug Administration (FDA) has approved GOCOVRI (amantadine) extended release capsules (previously ADS-5102) for treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. GOCOVRI, previously granted orphan drug status by the FDA, is the first and only medicine approved by the FDA for this indication.

"GOCOVRI's approval is an important advancement for the treatment of Parkinson's disease, as it is the first FDA-approved medicine for the treatment of dyskinesia in Parkinson's disease patients," said Rajesh Pahwa, M.D., Laverne & Joyce Rider Professor of Neurology at the Kansas Medical Center and Director, Parkinson's Disease Center of Excellence at the University of Kansas Health System. "Notably, GOCOVRI is the first Parkinson's disease medicine proven in controlled trials to reduce both dyskinesia and OFF time in Parkinson's disease patients receiving levodopa. Treatment of dyskinesia and OFF time continues to be an unmet need in the medical management of Parkinson's disease and the approval of GOCOVRI is a major step in that direction."

GOCOVRI is a high dose 274 mg amantadine (equivalent to 340 mg amantadine HCl) taken once-daily at bedtime that delivers consistently high levels of amantadine from the morning and throughout the day when dyskinesia occurs. Dyskinesia is a consequence of levodopa-based Parkinson's disease treatment and is characterized by involuntary and non-rhythmic movements that are purposeless and unpredictable, which impact the activities of daily living.

"Dyskinesia can significantly compromise quality of life for people with Parkinson's disease," said Dr. Todd Sherer, Chief Executive Officer of The Michael J. Fox Foundation for Parkinson's Research. "We are pleased that patients have another option to manage this aspect of the disease and glad the Unified Dyskinesia Rating Scale - a tool our support helped develop and validate - could show clinical efficacy of GOCOVRI for the treatment of dyskinesia."

GOCOVRI's positive benefit/safety profile was established in two Phase 3 controlled clinical trials in Parkinson's disease patients with dyskinesia. In Study 1, patients treated with GOCOVRI demonstrated statistically significant and clinically relevant reductions in dyskinesia, with a 37 percent reduction in Unified Dyskinesia Rating Scale (UDysRS) total score vs. 12 percent for placebo at Week 12. These results were confirmed in Study 2 in which GOCOVRI achieved a 46 percent reduction in UDysRS vs. 16 percent for placebo. Additionally, key secondary data from Parkinson's disease patient reported diaries in Study 1 and Study 2 respectively, showed that GOCOVRI-treated patients experienced a 3.6 and 4.0 hour increase in functional time daily (defined as ON time without troublesome dyskinesia) vs. a 0.8 and 2.1 hour increase for placebo-treated patients at Week 12. The increases in functional time were achieved by decreases in both ON time with troublesome dyskinesia and OFF time. The placebo-adjusted reduction in OFF time in both studies was approximately 1 hour per day. The most commonly observed adverse reactions (> 10 percent and greater than placebo) with GOCOVRI were hallucinations, dizziness, dry mouth, peripheral edema, constipation, fall and orthostatic hypotension. For additional Important Safety Information, see below.

"Today's approval is a tremendous milestone for Adamas and for the Parkinson's disease community," said Gregory T. Went, Ph.D., Founder, Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. "GOCOVRI has the potential to help people with Parkinson's disease suffering from dyskinesia by finally providing physicians with an effective tool to address this long-standing unmet medical need. We thank the physicians, clinical staff, patients and their families who participated in the clinical trials for making this advancement possible for the community."

GOCOVRI is expected to be available in the fourth quarter, and formally launched with the full deployment of Adamas's sales force in January 2018. Adamas developed GOCOVRI for people with Parkinson's disease and the company is committed to helping them gain access. Adamas has created "GOCOVRI Onboard," a patient services program, which will facilitate access and distribution. "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.

Investor Conference Call and Webcast

Adamas will host a conference call and webcast today, August 24, 2017, at 4:30 p.m. Eastern Time. The conference call may be accessed by dialing 844-215-3280 for participants in the U.S. or Canada and 484-747-6383 for international callers. The webcast can be accessed live via the investor section of the Adamas website at <http://ir.adamaspharma.com/events.cfm> and will be available for replay until September 24, 2017.

About Parkinson's Disease and Dyskinesia

Parkinson's disease is a chronic neurodegenerative disorder affecting close to one million people in the U.S. Parkinson's disease results from a loss of dopamine in the brain and is commonly treated by levodopa and dopaminergic therapies that help replace lost dopamine. As the disease progresses, people require increasingly higher or more frequent doses of levodopa in order to avoid the recurrent periods of OFF time - characterized by slowness of movement, rigidity, impaired walking, tremor and postural instability - when the underlying symptoms of Parkinson's disease return.

Over time, nearly 90 percent of people on levodopa therapy experience dyskinesia, which is characterized by involuntary and non-rhythmic movements during waking hours that are purposeless and unpredictable. Dyskinesia can interfere with people's daily living, resulting in functional impairment and disability. People with Parkinson's disease often experience multiple fluctuating periods of OFF time and dyskinesia during any given day, which can impede their movement and daily function. In the U.S., there are approximately 150,000 - 200,000 people with Parkinson's disease whose daily life is impacted by dyskinesia. Until now, physicians have had limited options to manage, and have had no approved medicines to treat dyskinesia.

About GOCOVRI

GOCOVRI 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 taken once-daily at bedtime, which delivers consistently high levels of amantadine in the morning and throughout the day when dyskinesia is most prevalent. GOCOVRI has received orphan drug status from the FDA. For more information about GOCOVRI, including the full Prescribing Information, please call 1-844-GOCOVRI [1-844-462-6874] or visit www.GOCOVRI.com.

About Adamas Pharmaceuticals, Inc.

At Adamas, we believe in the power and the promise of medicines derived from a deep understanding of time-dependent biology. Our expertise lies in uncovering and mapping the relationship between disease and drug activity. From there, we strive to create medicines with therapeutic profiles that match the pattern of disease to drive a more significant and durable clinical effect. This understanding of time-dependent biological processes informs our every innovation, targeting advancement in treatment of chronic neurologic disorders. Our portfolio includes: 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; ADS-5102 in development for the treatment of multiple sclerosis walking impairment and additional indications in Parkinson's disease, and ADS-4101, a high-dose, modified-release lacosamide in Phase 1 clinical development for the treatment of partial onset seizures in patients with epilepsy. Additionally, Adamas's licensed assets are currently marketed by Allergan under the brand names NAMENDA XR® and NAMZARIC®, and Adamas is eligible to receive royalties on sales of these medicines beginning in June 2018 and May 2020, respectively. For more information, please visit www.adamaspharma.com.

NAMENDA XR® and NAMZARIC® are trademarks of Merz Pharma GmbH & Co. KGaA.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

GOCOVRI™ 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.

Forward-looking Statements

Statements contained in this press release regarding expected future events 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 benefits of GOCOVRI, physician and patient access in fourth quarter 2017 and launch of GOCOVRI (amantadine) extended release capsules (previously ADS-5102) in January 2018 for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, and Adamas' plans to offer a number of programs providing patient access support throughout the course of treatment, along with commercial copay assistance and financial assistance for patients who are uninsured or underinsured. Words such as "potentially," "expected," "will," "plans" 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 ADS-5102 and ADS-4101, and 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 August 8, 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.

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