Jan 06, 2017

EMERYVILLE, Calif., Jan. 06, 2017 (GLOBE NEWSWIRE) -- Adamas Pharmaceuticals, Inc. (Nasdaq:ADMS) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for ADS-5102 (amantadine hydrochloride) extended-release capsules, for the treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson's disease. The ADS-5102 application has been given a Prescription Drug User Fee Act (PDUFA) target action date of August 24, 2017.

"This is an important milestone for patients, physicians and Adamas, as we are one step closer to approval of ADS-5102 for Parkinson's disease patients with levodopa-induced dyskinesia, which is an existing gap in their treatment journey," said Gregory T. Went, Ph.D., Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. "Over time, 90% of patients on levodopa therapy suffer from levodopa-induced dyskinesia. Currently, there is no FDA approved medicine for levodopa-induced dyskinesia for patients with Parkinson's disease. If approved, ADS-5102 will be the first and only medicine for Parkinson's disease patients with levodopa-induced dyskinesia."

The NDA for ADS-5102 was submitted in October 2016 and is supported by efficacy and safety data compiled from Adamas' full clinical program, which was designed to evaluate ADS-5102 for the treatment of LID in patients with Parkinson's disease. The comprehensive program included three placebo-controlled trials: EASED and two Phase 3 trials, EASE LID and EASE LID 3. The controlled Phase 3 data for ADS-5102 presented in the NDA demonstrate a primary reduction of LID and a secondary reduction in OFF time in Parkinson's disease patients, with a manageable safety and tolerability profile. The NDA is also supported by data from an open-label safety study known as EASE LID 2, which enrolled patients from EASED, EASE LID and EASE LID 3, as well as LID patients who have undergone deep brain stimulation. The EASE LID 2 trial is ongoing, and patients are being followed for up to two years.

About ADS-5102
ADS-5102 is a chrono-synchronous amantadine therapy for the potential treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson's disease. ADS-5102 is dosed once daily at bedtime to time the delivery of drug levels of amantadine to waking hours when LID episodes are most frequent and movement control is needed most. An NDA for ADS-5102 is currently under review by the FDA for the treatment of LID in patients with Parkinson's disease. In April 2015, the FDA granted orphan drug status to ADS-5102 for this indication. Adamas is also investigating ADS-5102 for other indications earlier in the Parkinson's treatment journey, as well as in walking impairment in multiple sclerosis. ADS-5102 may have broad utility in hyper- and hypokinetic disorders.

About Parkinson's Disease and Levodopa-induced Dyskinesia
Parkinson's disease is a chronic neurodegenerative disorder affecting close to 1 million people in the United States. It is characterized by the progressive loss of dopaminergic neurons, causing lower levels of endogenous dopamine and manifesting as symptoms of bradykinesia (slowness of movement), rigidity, impaired walking, tremor and postural instability. As a replacement therapy for the loss of dopaminergic neurons, levodopa is the most effective therapy for Parkinson's disease and is considered the "gold standard." As a result of disease progression and chronic levodopa therapy, nearly all Parkinson's disease patients will experience levodopa-induced dyskinesia (LID) depending on their levodopa dose. LID is characterized by involuntary movements that are non-rhythmic, purposeless, and unpredictable. In the U.S., approximately 150,000 to 200,000 Parkinson's patients suffer from LID at any given time, and over time, 90% of patients on levodopa therapy will develop it.

About Adamas Pharmaceuticals, Inc.
Adamas Pharmaceuticals develops new medicines to improve the daily lives of those affected by chronic neurologic
disorders, including Alzheimer's disease, Parkinson's disease, multiple sclerosis (MS) and epilepsy. Adamas has pioneered a platform to develop medicines, called chrono-synchronous therapies, for chronic neurologic disorders based on an understanding of time-dependent biologic effects of disease activity and drug response to potentially achieve symptomatic relief without additional tolerability issues. Its proprietary lead product candidate, ADS-5102, is in development for levodopa-induced dyskinesia in patients with Parkinson's disease and walking impairment in MS. Adamas is also investigating ADS-4101 for the improved control of epileptic seizures. Additionally, through its license agreement with Allergan, it is eligible to receive royalties on sales of NAMENDA XR® and NAMZARIC® beginning in June 2018 and May 2020, respectively. For more information, please visit www.adamaspharma.com.

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Forward-looking Statements
Statements contained in this press release regarding matters that are not historical facts 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 potential approval and commercialization of ADS-5102 for treatment of levodopa-induced dyskinesia in patients with Parkinson's disease, a potential registration program for ADS-5102 for treatment of walking impairment in MS, additional indications for ADS-5102, and additional products such as ADS-4101. Words such as "look forward," "on track," "expect," "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 our research, clinical and development activities relating to ADS-5102 and ADS-4101, the regulatory and competitive environment and our business in general, see our most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 3, 2016. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. We undertake no obligation to update any forward-looking statement in this press release.

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