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Adamas Announces Publication of ADS-5102 Phase 2 Clinical Trial Results in Multiple Sclerosis Journal

--Placebo-controlled proof-of-concept trial demonstrated that ADS-5102 significantly improved walking speed in multiple sclerosis patients with walking impairment--

EMERYVILLE, Calif., Feb. 01, 2018 (GLOBE NEWSWIRE) -- Adamas Pharmaceuticals, Inc. (Nasdaq:ADMS) today announced that results of its Phase 2 proof-of-concept clinical trial of ADS-5102 (amantadine) extended release capsules in multiple sclerosis (MS) patients with walking impairment were published online in *Multiple Sclerosis Journal.* Clinical data from the four-week, placebo-controlled, proof-of-concept study showed a statistically significant 17 percent improvement in walking speed from baseline and that a greater proportion of ADS-5102-treated patients experienced at least a 20 percent improvement in walking speed from baseline. The publication can be accessed at: http://journals.sagepub.com/doi/full/10.1177/1352458518754716

"In this proof-of-concept study, a greater proportion of ADS-5102 patients had at least a 20 percent improvement in walking speed compared with the placebo group," stated Jeffrey A. Cohen, M.D., Mellen Center for Multiple Sclerosis Treatment and Research, Neurological Institute, Cleveland Clinic, and a paid consultant for Adamas. "There is a need for additional, effective treatment options in this multiple sclerosis patient population, as currently, there is only one FDA-approved drug which is believed to be effective in only a subset of multiple sclerosis patients with walking impairment."

"We are pleased to have data from this important study available in a peer-reviewed journal and look forward to initiating the first Phase 3 clinical study of ADS-5102 in multiple sclerosis patients with walking impairment in the second quarter of 2018," stated Rajiv Patni, MD, Chief Medical Officer of Adamas Pharmaceuticals, Inc.

Phase 2 Proof-of-Concept Study Design and Results
The multi-center, randomized, placebo-controlled, Phase 2 proof-of-concept study was designed to evaluate ADS-5102 in MS patients with walking impairment for four weeks. The study enrolled 60 MS patients who had impaired walking speed at baseline and the primary objective was to evaluate the safety and tolerability of 274 mg ADS-5102 dosed once-daily at bedtime. Efficacy results were obtained from a modified intent-to-treat population that included 56 subjects who received at least one dose of ADS-5102 and provided at least one post-baseline walking assessment. An analysis using the mean changes from baseline to week four efficacy measures showed an approximate 17 percent placebo-adjusted improvement in mean walking speed, as assessed by Timed 25-Foot Walk (T25FW). In addition, the data demonstrated that a greater proportion of ADS-5102-treated patients experienced at least a 20 percent improvement in walking speed from baseline. Trends suggesting benefit, which did not reach statistical significance, were observed for the Timed Up and Go (TUG) and the 2 Minute Walk Test (2MWT).

ADS-5102 was generally well tolerated in this study population. One serious adverse event was reported in the study, suspected serotonin syndrome, reported as drug related by an investigator. The most frequent adverse events (AEs) reported in the ADS-5102 treatment group were dry mouth, constipation and insomnia. Five ADS-5102 patients and no placebo patients discontinued treatment due to AEs.

About Multiple Sclerosis and Walking Impairment[i]
Multiple sclerosis (MS) is a chronic autoimmune-mediated disorder and manifests as unpredictable symptoms that can vary in severity and tend to progress over years, in some cases to near total disability. Walking impairment affects a majority of the approximately 400,000 MS patients in the United States and remains an area of high unmet need, as there is only one approved product on the market for this indication.

About ADS-5102
ADS-5102 is a high-dose amantadine taken once-daily at bedtime, which delivers consistently high levels of amantadine in the morning and throughout the day. ADS-5102 was previously approved by the U.S. Food and Drug Administration (FDA) under the trade name 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, and is the first and only FDA-approved medicine for this indication.

About Adamas Pharmaceuticals, Inc.

Adamas is using its deep understanding of time-dependent biology to redefine the treatment experience for patients suffering from chronic neurological diseases. The company is 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 with a 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 neurological medicines intended to lessen the burden of disease on patients, caregivers and society. For more information about Adamas and its unique approach to developing medicines based on time-dependent biology, please visit www.adamaspharma.com.

Forward-looking Statements

Statements contained in this press release regarding matters 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 expectation of Adamas Pharmaceuticals to initiate the first Phase 3 clinical study of ADS-5102 in multiple sclerosis patients with walking impairment early in the second quarter of 2018 and the potential clinical benefits of ADS-5102. 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 and ADS-5102, the regulatory and competitive environment and Adamas' business in general, see Adamas' Current Report on Form 8-K filed with the Securities and Exchange Commission on January 22, 2018. 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.

[i] Sutliff 2010

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