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## **Adamas Presents Expanded Analysis from the ADS-5102 Open-Label Study Showing Tolerability and Durability out to 88 Weeks**

*-- New subgroup analyses showed that patients previously treated with amantadine IR received benefit of ADS-5102 comparable to patients previously treated with placebo --*

*-- New Drug Application supporting ADS-5102 for the treatment of levodopa-induced dyskinesia currently under FDA review with August 24, 2017, PDUFA date --*

EMERYVILLE, Calif., June 08, 2017 (GLOBE NEWSWIRE) -- Adamas Pharmaceuticals, Inc. (Nasdaq:ADMS) today announced the presentation of an updated analysis of efficacy and tolerability data from EASE LID 2, the company's ongoing Phase 3 open-label, long-term safety and efficacy study of ADS-5102 (amantadine) extended-release capsules. Overall, results demonstrated that ADS-5102 was well tolerated and the treatment effect on motor complications, as measured by the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS), Part IV score, was maintained for up to 88 weeks. Analyses of data from two subgroups of patients, those who have undergone prior deep brain stimulation (DBS) treatment and those who switched from amantadine immediate-release (IR) to open-label ADS-5102, both showed a rapid and sustained reduction in dyskinesia and OFF after introduction of ADS-5102. The analyses were presented in a poster session at the 21<sup>st</sup> International Congress of Parkinson's Disease and Movement Disorders in Vancouver, Canada.

"These long-term, open-label data are encouraging for physicians and their patients who are suffering from dyskinesia," said Dr. J. William Langston, M.D., Founder and Chief Scientific Officer of the Parkinson's Institute. "It is particularly noteworthy that patients who were switched from amantadine IR to ADS-5102 experienced continuing improvement in dyskinesia and OFF during this open-label study and that this improvement was comparable to that seen in patients who were switched from placebo to ADS-5102."

"The expanded analysis out to 88 weeks provides continued support for the long-term safety and tolerability of ADS-5102, as evidenced by a minimal discontinuation rate, and the maintenance of a reduced and nearly constant level of dyskinesia and OFF for over 12 months, as measured by MDS-UPDRS, Part IV," said Rajiv Patni, M.D., Chief Medical Officer of Adamas Pharmaceuticals, Inc. "These open-label data, taken together with the ADS-5102 Phase 3 data, suggest that ADS-5102 may have the potential to transform the treatment landscape for dyskinetic patients with Parkinson's disease treated with levodopa. If approved, ADS-5102 will be the first and only FDA-approved medicine indicated for the treatment of levodopa-induced dyskinesia in people with Parkinson's disease, and we look forward to making this treatment available to patients in need."

Expanding on previously reported 64-week data, this updated analysis demonstrated that the treatment effect of ADS-5102 on motor complications, as assessed by MDS-UPDRS, Part IV (a measurement of dyskinesia, OFF and dystonia), was durable and maintained at a constant level for up to 88 weeks. Among patients previously treated with amantadine IR, switching to open-label ADS-5102 provided a 3 point, statistically significant reduction in MDS-UPDRS Part IV at Week 8. The treatment effect experienced by patients previously treated with amantadine IR was similar to that experienced by previous placebo-treated patients, and was maintained for up to 64 weeks. Patients who have undergone prior DBS treatment and were switched to open-label ADS-5102 also demonstrated a comparable reduction in the MDS-UPDRS, Part IV. All subgroups achieved reductions in motor complications without compromising the underlying control of Parkinson's symptoms, as assessed by Parts I-III of the MDS-UPDRS.

The safety data are consistent with the previously reported safety profile of ADS-5102 and the known safety profile of amantadine, which includes precautions and warnings related to suicidality, hallucinations and dizziness. Approximately 50% of discontinuations due to adverse events (AEs) occurred within the first month of treatment. The most common AEs, occurring in five percent or more of patients in any group, included falls, visual hallucinations, peripheral edema, constipation, livedo reticularis, nausea, dry mouth, insomnia and dizziness.

### **About the EASE LID 2 Open-label Safety Study**

The EASE LID 2 study is an ongoing Phase 3 open-label, long-term safety study of ADS-5102 for the treatment of levodopa-induced dyskinesia (LID) in 223 patients with Parkinson's disease. The study enrolled patients from the three ADS-5102 placebo-controlled LID efficacy trials (EASED, EASE LID and EASE LID 3), as well as Parkinson's disease patients with LID who have undergone deep brain stimulation (DBS) treatment. Patients are being followed for up to two

years. The primary objective of the study is to characterize the long-term safety and tolerability of ADS-5102 dosed once daily at bedtime for the treatment of LID in patients with Parkinson's disease. Secondary objectives include evaluating the durability of ADS-5102 on motor complications (dyskinesia and OFF) as assessed by the MDS-UPDRS, Part IV, as well as evaluating the clinical progression of Parkinson's disease.

#### **About ADS-5102**

ADS-5102 is a high-dose amantadine, taken once daily at bedtime, in development for the treatment of LID in people with Parkinson's disease. A New Drug Application (NDA) supporting ADS-5102 for the treatment of LID in people with Parkinson's disease is under review by the U.S. Food and Drug Administration (FDA), with a Prescription Drug User Fee Act (PDUFA) date of August 24, 2017. If approved, ADS-5102 will be the first and only FDA-approved medicine indicated for the treatment of LID in people with Parkinson's disease. Adamas is also investigating ADS-5102 for the treatment of walking impairment in people with multiple sclerosis and is considering developing it for other indications earlier in the Parkinson's disease treatment journey.

#### **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.

Levodopa, which replaces lost dopamine, is the most effective therapy for all stages of Parkinson's disease and is considered the "gold standard" therapy. Over time, people require increasingly higher or more frequent doses of levodopa in order to avoid the recurrent periods of OFF time when the underlying symptoms of Parkinson's disease return. As Parkinson's disease progresses, nearly all people on levodopa therapy will also experience LID, which is characterized by involuntary movements that are non-rhythmic, purposeless and unpredictable. Symptoms of OFF time are characterized by slowness of movement, rigidity, impaired walking, tremor and postural instability. These people often experience multiple fluctuating periods of OFF time and LID during any given day, which can impede their movement and daily function. In the United States, approximately 150,000 to 200,000 people with Parkinson's suffer from LID.

#### **About Adamas Pharmaceuticals, Inc.**

Adamas develops new medicines to improve the daily lives of those affected by chronic neurologic disorders, including Parkinson's disease, multiple sclerosis, epilepsy, and Alzheimer's disease. Adamas has pioneered a platform to develop medicines for chronic neurologic disorders based on an understanding of the time-dependent biologic processes responsible for disease activity and drug response. The company's most advanced product candidate, ADS-5102, is a high-dose amantadine, taken once daily at bedtime, in development for levodopa-induced dyskinesia in people with Parkinson's disease and for the treatment of walking impairment in people with multiple sclerosis. A New Drug Application supporting ADS-5102 for the treatment of levodopa-induced dyskinesia in people with Parkinson's disease is under review by the FDA with a PDUFA date of August 24, 2017. Adamas is exploring other indications for further development of ADS-5102. Adamas is also investigating ADS-4101 for the treatment of partial onset seizures in patients with epilepsy. Additionally, Adamas' licensed assets, are currently marketed by Allergan under the brand names NAMENDA XR<sup>®</sup> and NAMZARIC<sup>®</sup>, 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](http://www.adamaspharma.com).

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#### **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 potential approval of ADS-5102 for the treatment of levodopa-induced dyskinesia in people with Parkinson's disease 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 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 May 9, 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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