February 19, 2018

Adamas Announces Declaratory Judgment Action Filed by Osmotica Related to Approved OSMOLEX ER

EMERYVILLE, Calif., Feb. 19, 2018 (GLOBE NEWSWIRE) -- Adamas Pharmaceuticals, Inc. (NASDAQ:ADMS) announced today that it has learned that Osmotica Pharmaceuticals LLC and Vertical Pharmaceuticals LCC (Osmotica) filed an action in Delaware federal court on February 16, 2018 requesting a declaratory judgment that Osmotica's newly-approved product OSMOLEX ER™ (amantadine) extended-release tablets does not infringe certain of Adamas' patents. Adamas has not received service of a summons and complaint. The complaint does not allege patent infringement against Adamas or otherwise pertain to Adamas' product GOCOVRI™ (amantadine) extended release capsules.

OSMOLEX ER was approved by the U.S. Food and Drug Administration (FDA) on February 16, 2018 for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adult patients, indications approved for immediate release amantadine in 1972. As Osmotica states in the complaint, drug-induced extrapyramidal reaction is a separate and distinct disorder from dyskinesia in Parkinson's disease patients. According to the package insert attached to the complaint, the approval was based on three bioavailability studies comparing OSMOLEX ER to immediate release amantadine syrup in healthy volunteers. The package insert does not include any new clinical safety or efficacy data specific to OSMOLEX ER to support its use in the approved indications. Osmotica alleges that OSMOLEX ER does not infringe certain of Adamas' patents covering compositions and uses of amantadine. Adamas is evaluating Osmotica's non-infringement assertions based on the limited information in the complaint.

Adamas' approved product GOCOVRI is the first and only FDA-approved medicine for the treatment of dyskinesia in Parkinson's disease patients on levodopa-based therapy, with or without concomitant dopaminergic medicines. GOCOVRI is taken at bedtime with a pharmacokinetic (PK) profile that delivers low concentrations of amantadine in nighttime, slowly rising to high concentrations (1,500 ng/ml) before awakening, and throughout the day. Use of GOCOVRI in this Parkinson's disease patient population is supported by robust efficacy and safety data, required by the FDA for approval, that demonstrate statistically significant and clinically meaningful reductions in dyskinesia and OFF time in three controlled clinical studies and an ongoing two-year, open-label safety study. Neither OSMOLEX ER nor any other therapy has been approved for the treatment of dyskinesia in Parkinson's disease patients on levodopa-based therapy.

Investor Conference Call and Webcast
As previously announced, Adamas will report fourth quarter and full year 2017 financial results on Thursday, February 22, 2018 after market close. Subsequently, Adamas' management team will host a conference call and webcast at 4:30 p.m. Eastern Time to discuss the financial results and provide a corporate update. The conference call can 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 March 22, 2018.

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.

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