May 22, 2017

Adamas Presents Positive Phase 1a Data of ADS-4101 (lacosamide) for the Treatment of Partial Onset Seizures in Epilepsy

-- Phase 1 results show ADS-4101 is better tolerated in healthy volunteers than equivalent doses of VIMPAT® (lacosamide) immediate-release tablets --

-- Multi-dose Phase 1b steady state study ongoing, with topline data expected in the third quarter 2017--

EMERYVILLE, Calif., May 22, 2017 (GLOBE NEWSWIRE) -- Adamas Pharmaceuticals, Inc. (Nasdaq:ADMS) today announced a presentation of positive data from the Phase 1a clinical trial of ADS-4101 (lacosamide) modified-release capsules, in a podium presentation at the 14th Antiepileptic Drug and Device Trials Conference. ADS-4101 was derived from the company's drug development platform and is in development for the treatment of partial onset seizures in patients with epilepsy. This Phase 1a study showed that single 400 mg doses of ADS-4101 in healthy volunteers have improved tolerability compared to the equivalent dose of VIMPAT® (lacosamide) immediate-release (IR) tablets. The data informed the selection of a formulation that is suitable for further clinical evaluation.

"We have successfully confirmed our hypothesis that the rapid initial rise in blood levels contributes to the adverse event profile of lacosamide, allowing us to advance ADS-4101 forward in clinical development," said Gregory T. Went, Ph. D., Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. "The goal of this program is to achieve higher levels of lacosamide throughout the day when we believe patients with epilepsy are most prone to seizures with similar or better tolerability than VIMPAT (lacosamide). ADS-4101 could potentially be the fourth product to emerge from Adamas' proprietary drug development platform, and potentially a second product for Adamas to commercialize for the benefit of patients with neurologic disorders."

ADS-4101 Phase 1a Trial Results
The ADS-4101 Phase 1a study was an open-label, single dose, cross-over study in 24 healthy volunteers that was designed to assess the pharmacokinetics (PK) and tolerability of four 400 mg dose formulations of ADS-4101 compared with VIMPAT tablets and to guide the selection of an ADS-4101 formulation for further clinical development.

Data from the study showed all four formulations of ADS-4101 to be safe and well tolerated when compared to the VIMPAT-treated group. Table 1 displays the most common adverse events occurring within 24 hours for all four formations of ADS-4101 compared to VIMPAT-treated patients following a single 400mg dose. Most adverse events for VIMPAT occurred within the first four hours following treatment.

Table 1. Adverse Events for ADS-4101 formulations compared to VIMPAT (lacosamide) IR tablets

	ADS-4101 Formulations				VIMPAT
	1	2	3	4	
	400 mg (N=12)	400 mg (N=12)	400 mg (N=12)	400 mg (N=10)	400 mg (N=24)
Subjects with At Least One Adverse Event within 24 Hours	16.7%	33.3%	16.7%	10.0%	62.5%
Most Common AEs with onset within 24 Hours by Preferred Term					
Hypoesthesia, oral	0.0%	8.3%	0.0%	0.0%	45.8%
Dizziness	8.3%	8.3%	8.3%	10.0%	33.3%

The Phase 1a study also showed that the ADS-4101 formulations have a slower rise and prolonged time to maximum plasma concentrations (T_{max}) compared to VIMPAT tablets. The time to max plasma concentrations for the ADS-4101 formulations ranged from 9.5 - 17.0 hours compared to 0.5 - 1.0 hour for VIMPAT tablets. The data from the Phase 1a study guided the company's decision to select a formulation for further clinical evaluation, which is well tolerated, rises slowly and has a 15-hour time to maximum concentration.

"With this positive data in hand, coupled with our understanding that epileptic seizures primarily occur during the day, we have advanced our program to evaluate three ascending doses of ADS-4101 in healthy volunteers," said Rajiv Patni, M.D., Chief Medical Officer of Adamas Pharmaceuticals, Inc. "The ongoing Phase 1b steady state study is designed to establish

the dose and titration schedule of ADS-4101 given once daily at bedtime. We look forward to topline data from this study in the third quarter, with the goal of advancing to clinical studies in epilepsy patients following a meeting with FDA."

ADS-4101 Phase 1b Clinical Trial Design
Based on positive findings from the Phase 1a study of ADS-4101, Adamas has initiated a multi-dose Phase 1b study designed to evaluate the tolerability and PK profile of three ascending doses of ADS-4101 administered once daily at bedtime compared to ascending doses of twice daily VIMPAT tablets in 24 healthy volunteers. The objectives of the study are to determine the steady-state PK parameters of the three dose levels of ADS-4101 and three dose levels of VIMPAT tablets as well as to compare overall safety and tolerability of ADS-4101 versus VIMPAT tablets. Over a three-week period, ADS-4101 is dosed once daily at nighttime starting at 200 mg for Week 1, increasing to 400 mg for Week 2 and 600 mg in Week 3, compared to twice daily doses of VIMPAT tablets at 100 mg twice daily in Week 1, 150 mg twice daily in Week 2 and 200 mg twice daily in Week 3. Topline data from the ADS-4101 Phase 1b study are expected in the third quarter of 2017.

About ADS-4101[i]
There is an important need for new, clinically differentiated treatment options for epilepsy, a chronic neurologic disorder characterized by recurrent unprovoked seizures, affecting an estimated 2.2 million Americans. Nearly two-thirds of epilepsy patients suffer from partial onset seizures, which affect one side of the brain. Despite advances, nearly one-third of epilepsy patients continue to suffer from seizures.

ADS-4101 is an investigational drug in development for the treatment of partial onset seizures in patients with epilepsy. Derived from Adamas' development platform, ADS-4101 is a high strength lacosamide therapy administered once daily at bedtime. Lacosamide is an anti-epilepsy active ingredient previously approved by the U.S. Food and Drug Administration and currently marketed as VIMPAT® (lacosamide). ADS-4101 is designed to deliver high concentrations of medicine during the day when seizures primarily occur and achieve higher drug levels throughout the day when Adamas believes patients with epilepsy are most prone to seizures, with similar or better tolerability than VIMPAT.

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 to potentially achieve symptomatic relief without tolerability issues. 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 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 of ADS-5102 for further development. 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® 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.

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 additional data on ADS-4101, and potential efficacy and safety of ADS-4101 for the treatment of partial onset seizure in patients with epilepsy. Words such as "expect," "anticipate," 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 the timing and potential success its products, including ADS-4101; the regulatory and competitive environment for products covered by patents with limited term and scope of exclusivity protection; and Adamas' business in general, see Adamas' Annual Report on Form 10-K 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.

[i] *Epilepsy Foundation of America 2016; Datamonitor Epidemiology Report 2013 American Association of Neurological Surgeons 2016*

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