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Adamas Announces Topline Phase 1b Data of ADS-4101 (lacosamide) for the Treatment of Partial Onset Seizures in Epilepsy

-- ADS-4101 600 mg achieved higher lacosamide plasma concentration throughout the day and comparable tolerability relative to the approved maximum dose (400 mg) of VIMPAT® (lacosamide) immediate-release tablets, in healthy volunteers --

EMERYVILLE, Calif., Sept. 07, 2017 (GLOBE NEWSWIRE) -- Adamas Pharmaceuticals, Inc. (Nasdaq:ADMS) today announced positive topline data from the Phase 1b clinical trial of ADS-4101 (lacosamide) modified-release capsules. The study demonstrated that a 600 mg dose of ADS-4101, taken once-nightly, provided a 1.7-fold increase in average lacosamide concentrations throughout the day compared to the maximum approved daily dose of 400 mg, taken as 200 mg twice-daily (BID), of VIMPAT® (lacosamide) immediate-release tablets in healthy volunteers, with comparable tolerability. ADS-4101 is an investigational drug in development for the treatment of partial onset seizures in patents with epilepsy.

"There is an important need for new, clinically meaningful treatment options for patients with epilepsy as even despite advances, patients continue to suffer from seizures," said Rajiv Patni, MD, Chief Medical Officer of Adamas Pharmaceuticals, Inc. "The healthy volunteer steady-state data suggest that lacosamide concentrations achieved with the 600 mg once-nightly dose of ADS-4101 are well above both the minimum concentration and maximum concentration achieved with the highest approved dose of VIMPAT, taken as 200 mg twice-daily."

"ADS-4101 is the fourth product developed from our validated time-dependent biology approach. The Phase 1 results confirm ADS-4101's innovative steady state pharmacokinetic profile, which provides high drug concentrations during the day to match the diurnal pattern of seizures, with lower levels at night when seizures are less frequent," stated Gregory T. Went, Ph.D., Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. "We look forward to sharing these results with the epilepsy community and discussing the next steps for the ADS-4101 program with the FDA at an End-of-Phase 2 meeting."

ADS-4101 Phase 1b Clinical Trial Data
The ADS-4101 Phase 1b study was designed to evaluate the tolerability and steady state pharmacokinetic (PK) profile of three ascending doses of ADS-4101 compared to ascending doses of VIMPAT in 24 healthy volunteers. The objectives of the study were to determine the steady-state PK parameters of three dose levels of ADS-4101 and three dose levels of VIMPAT as well as to compare overall safety and tolerability of ADS-4101 versus VIMPAT. ADS-4101 was dosed once-nightly starting at 200 mg for Week 1, increasing to 400 mg for Week 2 and 600 mg in Week 3, compared to VIMPAT dosed per its label at doses of 200 mg in Week 1, 300 mg in Week 2 and 400 mg in Week 3, all taken twice-daily in equal divided doses. ADS-4101 exhibited a plasma concentration-time profile characterized by a slow initial rise in plasma concentrations overnight that peaked the following morning and were sustained throughout the day. At the 600 mg dose, ADS-4101 provides a 1.7-fold increase in average lacosamide concentration throughout the day compared to 400 mg daily, taken as 200 mg BID, of VIMPAT.

ADS-4101 was safe and well-tolerated across all three doses, with the highest dose of ADS-4101 (600 mg) demonstrating equivalent tolerability when compared to a lower dose of VIMPAT (400 mg, taken as 200 mg BID). The types of central nervous system/psychiatric adverse events (AEs) reported during the ADS-4101 treatment were consistent with the known VIMPAT safety profile in healthy volunteers. For known VIMPAT AEs (oral hypoesthesia, dizziness, abnormal dreams, and euphoria), incidences were comparable or lower for 600 mg ADS-4101 versus 400 mg VIMPAT, and the number of subjects with these AEs were small (< 10%).

About ADS-4101
ADS-4101 is an investigational drug in development for the treatment of partial onset seizures in patients with epilepsy. Derived from Adamas's validated time-dependent biology approach to drug development, ADS-4101 is a potential high-dose, once-nightly lacosamide therapy, with a drug profile that provides high concentrations of lacosamide during the day to match the time when seizures occur most often. Lacosamide is an anti-epilepsy active ingredient previously approved by the U.S. Food and Drug Administration (FDA) and currently marketed as VIMPAT (lacosamide).

About Adamas Pharmaceuticals, Inc.
At Adamas, we believe in the power and the promise of medicines derived from a deep understanding of time-dependent

biology. Our expertise lies in uncovering and mapping the relationship between disease and drug activity. From there, we strive to create medicines with therapeutic profiles that match the pattern of disease to drive a more significant and durable clinical effect. This understanding of time-dependent biological processes informs our every innovation, targeting advancement in treatment of chronic neurologic disorders. Our portfolio includes: 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 receiving levodopa-based therapy, with or without concomitant dopaminergic medications; ADS-5102 in development for the treatment of multiple sclerosis walking impairment, and ADS-4101, a high-dose, modified-release lacosamide in Phase 1 clinical development for the treatment of partial onset seizures in patients with epilepsy. Additionally, Adamas's 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.

Contact:

Ashleigh Barreto

Director, Corporate Communications & Investor Relations

Adamas Pharmaceuticals, Inc.

Phone: 510-450-3567

Email: ir@adamaspharma.com

Primary Logo

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