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Zosano Pharma Announces Initiation of Long-Term Safety Study for M207 as an Acute Treatment of Migraine

FREMONT, Calif., Nov. 08, 2017 (GLOBE NEWSWIRE) -- Zosano Pharma Corp. (NASDAQ:ZSAN) ("Zosano" or the "Company") a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to subjects using its proprietary Adhesive Dermally-Applied Microarray ("ADAM") technology, announced the initiation of a long-term safety study, our M207-ADAM Study, which is designed to assess the safety profile of repeat uses of M207 for up to 12 months.

M207-ADAM is an open label study evaluating the safety of the 3.8mg dose of zolmitriptan in migraine patients who have historically experienced at least 2 migraines per month. Patients are expected to treat a minimum of two migraines per month, with no maximum treatment limits. The study will evaluate 150 patients for six months, and 50 patients for a year at approximately 30 sites in the U.S. The Company may elect to enroll more than the required number of patients to ensure a robust data set, and achievement of evaluable patients at each time point. The primary objective of the study is to assess safety of M207 during repeated use over 6 and 12 months.

"We are pleased to have our first patient in M207-ADAM. This study marks the major component of the final phase of clinical development for M207, prior to filing our NDA," said John Walker, Chairman and Chief Executive Officer of Zosano. "While the trial's main purpose is to assess safety, we will also be evaluating patient usage patterns and additional data that could be very informative to our marketing plans, if M207 is approved by the FDA. The open label design of this trial will also allow us to provide details of the study periodically throughout 2018, which we intend to share with stakeholders in Zosano."

ADAM is Zosano Pharma's proprietary, investigational technology platform designed to offer rapid drug absorption into the bloodstream, which can result in an improved pharmacokinetic profile compared to original dosage forms. ADAM consists of an array of drug-coated titanium microprojections mounted on an adhesive backing that is pressed on to the skin using a reusable handheld applicator. The microprojections penetrate the stratum corneum and allow drug to be absorbed into the microcapillary system of the blood.

About Migraine

Migraine is the leading cause of disability among neurological disorders in the United States according to the American Migraine Foundation. Migraine symptoms can include moderate to severe headache pain combined with nausea and vomiting, or abnormal sensitivity to light and sound. According to the Migraine Research Foundation, migraine affects 30 million men, women and children in the United States. Most migraines last between four and 24 hours, but some last as long as three days. According to published studies, 63% of migraine patients experience between one and four migraines per month. According to Decision Resources, prescription drug sales for migraine in the top seven countries were estimated to be \$3.3 billion in 2015, and are expected to grow to \$4.4 billion in 2020. Triptans, a family of tryptamine-based drugs first sold in the 1990s, account for almost 75% of anti-migraine therapies prescribed at office visits.

About M207

M207 is our proprietary formulation of zolmitriptan delivered utilizing Zosano's proprietary Adhesive Dermally-Applied Microarray, or ADAM technology. Zosano's ADAM technology consists of titanium microprojections coated with drug, and in the case of M207, our formulation of zolmitriptan. Our ADAM technology delivers drug by abrading the stratum corneum and allowing drug to be absorbed into the microcapillary system of the skin. In February 2017, the Company announced statistically significant results from the ZOTRIP trial, which demonstrated that the 3.8mg dose of M207 met both co-primary endpoints, achieving pain freedom and most bothersome symptom freedom at 2 hours.

About Zosano Pharma

Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM technology. The Company recently announced positive results from our ZOTRIP study that evaluated M207, which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. Zosano is focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, for markets where patients remain underserved by existing therapies. The Company

anticipates that many of its current and future development programs may enable the Company to utilize a regulatory pathway that would streamline clinical development and accelerate the path towards commercialization. Learn more at www.zosanopharma.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding the timing of expected clinical development milestones, sufficiency of our capital resources and need for future funding and other future events and expectations. Readers are urged to consider statements that include the words "may," "will," "would," "could," "should," "might," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," "unaudited," "approximately" or the negative of those words or other comparable words to be uncertain and forward-looking. These statements are subject to risks and uncertainties that are difficult to predict and actual outcomes may differ materially. These include risks and uncertainties, without limitation, associated with the process of discovering, developing and commercializing products that are safe and effective for use as human therapeutics, risks inherent in the effort to build a business around such products and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent annual report on Form 10-K.. Although we believe that the expectations reflected in these forward-looking statements are reasonable, we cannot in any way guarantee that the future results, level of activity, performance or events and circumstances reflected in forward-looking statements will be achieved or occur. All forward-looking statements are based on information currently available to Zosano and Zosano assumes no obligation to update any such forward-looking statements.

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