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Zosano Reaches Enrollment Milestone in M207-ADAM Long-term Safety Study

103 patients have enrolled in study

FREMONT, Calif., March 16, 2018 (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, today announced that the 100th patient has enrolled and received M207 in the long-term safety study for the acute treatment of migraine. M207 is Zosano's lead development candidate. 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 at least 150 patients for six months, and 50 patients for a year at 31 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 the requisite number of evaluable patients completing 6 and 12 months. The primary objective of the study is to assess safety of M207 during repeated use over 6 and 12 months. M207-ADAM study updates include:

- 103 patients have qualified and received study drug
- additional 77 patients have signed consents and are in the 2-week run-in evaluation period
- study patients have treated 278 migraines since study initiation

"Our clinical investigators are doing an excellent job in patient recruitment and follow-up and we are pleased with the study's progress," said Dr. Donald Kellerman, Zosano's VP, Clinical Development and Medical Affairs. "We have reached an important milestone in our M207-ADAM study. With the 100th patient enrolled, we project that 12 months from now, at least 50 of these patients will complete the study and have treated at least two migraines per month. Our investigator partners will continue enrolling to reach a sufficient number of patients such that 150 patients will complete six months, but the clinical completion of the study will occur after 50 subjects have completed a year, which we estimate to be in one year."

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 penetrating 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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