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

250 subjects have enrolled in the Study

The Study is set to complete enrollment on May 18th

FREMONT, Calif., May 14, 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 250th subject has enrolled and received M207 in the M207-ADAM study (the "Study"), a long-term safety study for the acute treatment of migraines. Enrollment in the Study will close on May 18th; however, the investigators will continue enrolling subjects that are scheduled or currently in the run-in period.

The Study is an open label study evaluating the safety of the 3.8mg dose of zolmitriptan in migraine subjects who have historically experienced at least two migraines per month. Subjects are expected to treat a minimum of two migraines per month, with no maximum treatment limits. The Study will evaluate at least 150 subjects for six months and 50 subjects for a year at 31 sites in the U.S. The Company may elect to enroll more than the required number of subjects to ensure a robust data set, and achievement of the requisite number of evaluable subjects 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.

The M207-ADAM study updates include:

- 250 subjects have qualified and received study drug;
- An additional 60 subjects have signed consents and are in the 2-week run-in evaluation period;
- Subjects have treated over 1,000 migraines since the Study was initiated;
- Treatment has resulted in observed pain freedom at two hours in 42% of migraines and pain relief at two hours in 85% of migraines; and
- No serious adverse events have been observed to date.

"The M207-ADAM study continues to progress at a brisk pace. Importantly, our observed pain freedom and pain relief score at two hours are consistent with the data reported in our pivotal efficacy study," said Dr. Donald Kellerman, Zosano's VP, Clinical Development and Medical Affairs. "The 250th enrolled subject is an important milestone in the study. We believe that at least 150 subjects will complete six months of evaluation in the Study and 50 will complete one year. The Study is on track to have more than 50 subjects complete one year of evaluation by the end of March 2019."

About Migraine
Migraine is the leading cause of disability among neurological disorders in the United States according to the American Migraine Foundation. An estimated 36 million American adults suffer from migraine. Migraine can be extremely disabling and costly, accounting for more than an estimated $20 billion in direct (e.g., doctor visits, medications) and indirect (e.g., missed work, lost productivity) expenses each year in the United States.

About M207
M207 is Zosano's proprietary zolmitriptan-coated microneedle patch that is designed to rapidly deliver zolmitriptan during a migraine attack. In a phase 1 trial, M207 demonstrated markedly faster absorption kinetics compared to oral zolmitriptan. The Company presented these results at the 2016 annual meeting of the American Headache Society.

About Zosano Pharma
Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to subjects using our proprietary ADAM technology. The Company previously 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, and is currently conducting a long-term safety study of M207. Zosano is focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to subjects, for markets where subjects remain underserved by existing therapies. The Company anticipates that 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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