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Zosano Pharma Announces 3.8mg Dose of M207, its Novel Transdermal Therapeutic, Meets Both Co-primary Endpoints in the ZOTRIP Pivotal Efficacy Trial in Migraine

41.5% of patients experienced freedom from pain at 2 hours vs. 14.3% for placebo (p < 0.0001)

68.3% of patients experienced freedom from most bothersome symptom at 2 hours vs. 42.9% for placebo (p < 0.0009)

26.8% of patients experienced freedom from pain at 1 hour vs. 10.4% for placebo (p < 0.0084)

FREMONT, Calif., Feb. 13, 2017 (GLOBE NEWSWIRE) -- Zosano Pharma Corporation (NASDAQ:ZSAN) announces that its lead product candidate, M207, achieved both co-primary endpoints of pain freedom and most bothersome symptom freedom at 2 hours in the recently completed ZOTRIP trial. The ZOTRIP pivotal efficacy study was a multicenter, double-blind, randomized, placebo-controlled, dose-ranging trial comparing three doses (1.0mg, 1.9mg and 3.8mg) of M207, a novel transdermal therapeutic, to placebo for a single migraine attack. A total of 589 subjects were enrolled at 36 sites across the US. The 3.8mg dose achieved significance in the secondary endpoints of pain freedom at 45 minutes and 1 hour and showed durability of effect on pain freedom at 24 and 48 hours. Additionally, M207 was not associated with any Serious Adverse Events (SAEs).

The 3.8mg dose of M207 achieved statistical significance for both co-primary endpoints at two hours:

Primary endpoint	Placebo	3.8mg M207	p-value
Pain freedom	14.3%	41.5%	0.0001
Most bothersome symptom free	42.9%	68.3%	0.0009

Furthermore, secondary endpoints measuring pain freedom at additional time points for the 3.8mg dose of M207 showed M207 superior to placebo with a nominal p-value less than 0.05:

Pain Freedom	Placebo	3.8mg M207	p-value*
Pain freedom at 45 minutes	5.2%	17.1%	0.0175
Pain freedom at 60 minutes	10.4%	26.8%	0.0084
Pain freedom at 24 hours	39.0%	69.5%	0.0001
Pain freedom at 48 hours	39.0%	64.6%	0.0013

M207 was well-tolerated with no SAEs

- Overall, 13 subjects (3.9%) reported pain at the application site; application site pain was reported as mild in all but 3 subjects;
- The most frequently reported adverse event was redness at the application site (18.3% of subjects). All cases of redness resolved;
- Additionally, 5 (1.5%) patients across M207-treated groups reported dizziness vs 0% on placebo.

Stewart Tepper, MD, Professor of Neurology, Geisel School of Medicine at Dartmouth and Director of the Dartmouth Headache Clinic commented, "The ZOTRIP study was successful from the dual perspectives of meeting the co-primary endpoints and no serious adverse events. The study demonstrated a statistically significant 2-hour pain freedom response rate with a low placebo rate for the primary endpoint. The data also indicate a durability of effect at 24 and 48 hours, and meaningful pain freedom rate at 1 hour. If approved by the FDA, M207 has the potential to become an important treatment option for those suffering from migraine."

A PDF accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/45722c3f-e41a-4c21-826c-4721615c30cd

Overall, higher pain freedom rates were achieved on all doses after 60 minutes over placebo. While the 1.0mg and 1.9mg doses of M207 produced p-values less than 0.05 in pain freedom at two hours, they did not produce a p-value below 0.05

for the co-primary endpoint of freedom from most bothersome symptom at two hours.

"ZOTRIP was designed to be a dose-ranging study, as well as a registration study. We are very pleased by the results for the 3.8mg dose, and look forward to continuing the development of M207 towards filing an NDA and working to bring this novel therapy to patients suffering from the incapacitating effects of migraines," said Konstantinos Alataris PhD, President and Chief Executive Officer of Zosano.

The ZOTRIP Phase 3 Trial Design:

The ZOTRIP pivotal efficacy study was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of M207 (1.0mg, 1.9mg, and 3.8mg) to placebo for the treatment of a single migraine attack. Subjects were enrolled in the ZOTRIP trial at 36 centers across the United States. Those recruited into the trial had a history of at least one year of migraine episodes with or without aura. Upon recruitment, the subjects entered a run-in period that ensured they met the key eligibility criteria of 2-8 migraine attacks per month, which was documented using an electronic diary or an app on their cell phone. Subjects also identified their most bothersome symptom and indicated the presence or absence of nausea, phonophobia or photophobia, during the episodes in the run-in period. Successfully screened subjects were then randomized into the treatment/dosing period in which they had 8 weeks to confirm and receive blinded treatment for a single migraine attack, termed "qualifying migraine." In which the most bothersome symptom had to be present.

During a qualifying migraine, subjects scored the severity of pain on a 4-point scale, and the presence or absence of migraine associated symptoms (photophobia, phonophobia or nausea), starting pre-dose and then at several intervals over 48 hours post-dose.

Five hundred and eighty nine subjects were enrolled in this study, of which 365 were randomized. Of those randomized, 333 subjects treated and are included in the safety analysis, and 321 qualified for the modified intent-to-treat (mITT) population. 51% of the subjects randomized were found to have severe migraine pain pre-treatment. Also at the time of treatment, 70% reported nausea, 37% aura, and 51% waking up with their migraine (morning migraine). With the multiple doses and multiple endpoints in the trial, a sequential testing procedure was used beginning with the highest dose and the co-primary endpoints. Since statistical significance was not achieved for most bothersome symptom in the 1.9 mg group, p-values for secondary endpoints should be considered nominal p-values.

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 an emerging CNS company focusing on providing rapid symptom relief to patients using known therapeutics and altering their delivery profile using the Company's proprietary intracutaneous delivery system. The Company's goal is to make intracutaneous drug delivery a standard of care for delivering drugs requiring fast onset of action. Zosano Pharma has developed its proprietary intracutaneous delivery system to administer proprietary formulations of existing drugs through the skin for the treatment of a variety of indications. The Company believes that its intracutaneous delivery system offers rapid and consistent drug delivery combined with ease of use. The Company is focused on developing products that deliver established molecules with known safety and efficacy profiles for markets where patients remain underserved by existing therapies. Zosano Pharma 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, the likelihood that M207 is approved by the FDA and, if approved, the potential of M207 as a treatment for migraine 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," "designed," "goal," "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 our 2015 Annual Report on Form 10-K, as filed with the Securities Exchange Commission on March 29, 2016. In addition, the results of the M207 pivotal trial are not necessarily predictive of results in future trials. 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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