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Zosano Presents Additional Data from ZOTRIP Study at American Headache Society, Demonstrating Positive Results for Pain Freedom and Sustained Pain Freedom

FREMONT, Calif., June 12, 2017 (GLOBE NEWSWIRE) -- Zosano Pharma Inc. (NASDAQ:ZSAN) ("Zosano" or the "Company") a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary ADAM technology, presented additional data from its pivotal Phase 2/3 ZOTRIP study evaluating M207 as an acute treatment for migraine during the 59th Annual Scientific Meeting of the American Headache Society in Boston, MA. The data were presented Saturday during the late-breaking session by Egilius Spierings, M.D., Ph.D., a clinical investigator for the study and a Clinical Professor of Neurology and Craniofacial Pain at Tufts University Schools of Medicine and Dental Medicine.

As previously reported, the 3.8mg dose of M207 achieved both co-primary endpoints of pain freedom and most bothersome symptom freedom at 2 hours. In addition, 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. The data presented at AHS demonstrated that these results were attained with no SAEs and a favorable tolerability profile.

M207 is designed to rapidly deliver zolmitriptan during a migraine attack 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 zolmitriptan by abrading the stratum corneum and allowing drug to be absorbed into the microcapillary system of the skin.

"Zolmitriptan is one of the most potent triptans with regard to binding affinity at both 5HT-1d and 5HT-1b, and gains a secondary effect on both of these receptors through its active metabolite[1]. The novel delivery of zolmitriptan via our ADAM technology, our M207 product candidate, results in more rapid plasma levels compared to oral zolmitriptan, which may impact receptor binding or CNS penetration and suggests the rationale for demonstrated efficacy at the pre-specified endpoints," said Don Kellerman, Zosano's Vice President, Clinical Development and Medical Affairs. "M207 produced statistically significant results versus placebo for our co-primary endpoints, and a nominal p value of less than 0.05 for pain freedom at all time points from 45 minutes to 48 hours post dosing. This rapid onset and sustained freedom from pain positions Zosano's M207, if approved by the FDA, as a potential important new approach to treating migraines."

Zosano's novel delivery of zolmitriptan was confirmed by the results from the ZOTRIP study, where 41.5% of the patients treated with the 3.8mg dose of M207 achieved pain freedom at 2 hours, and the effect also appeared to be durable, with 31.7% and 26.8% of patients achieving sustained pain freedom from 2-24 hours and 2-48 hours respectively. In post-hoc analyses, M207 also demonstrated efficacy in traditionally difficult to treat established migraine headaches, as evidenced by a nearly identical therapeutic effect in those who treated prior to and after 2 hours. Additionally, 44% of patients who awoke with their migraine headache were pain-free at 2 hours. Patients in this trial were instructed not to treat until their headache reached moderate to severe intensity and the mean time from headache onset to treatment was almost 5 hours.

The ZOTRIP Study

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.

ZOTRIP Results

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.

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.

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.

[1]Tokuoka, Kentaro et al. "Theory-Based Analysis of Clinical Efficacy of Triptans Using Receptor Occupancy." *The Journal of Headache and Pain* 15.1 (2014): 85.

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