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Zosano Announces Publication of Positive Phase 1 Data of Zolmitriptan Delivery In Future Medicine's Pain Management Journal

FREMONT, Calif., July 31, 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 subjects using its proprietary Adhesive Dermally-Applied Microarray ("ADAM") technology, announced today that Future Medicine's Pain Management Journal had published the Company's positive results from a Phase 1, single center, open label, ascending-dose trial demonstrating the rapid and reproducible delivery of M207, our formulation of zolmitriptan using our ADAM technology.

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 skin.

The pharmacokinetics of zolmitriptan delivery using this technology was evaluated in 20 healthy volunteers in a phase 1 trial and median T_{max} (20 min) of M207 was shown to be similar to subcutaneous sumatriptan. Relative to oral zolmitriptan, absorption was substantially faster, with higher exposure in the first 2 hours when using M207. Most adverse events were consistent with those seen in previous triptan trials and no serious adverse events were observed. Application site reactions evaluated 30 minutes after application were generally mild and resolved within 24 hours. This study also demonstrated the feasibility of loading up to 3.8mg of zolmitriptan on the single array while maintaining the pharmacokinetic advantage described.

"These published results clearly demonstrate the unique pharmacokinetic profile generated by delivering zolmitriptan using our ADAM technology," stated Donald Kellerman, Zosano's Vice President of Clinical Development and Medical Affairs. "Confirmation that this pharmacokinetic profile could translate to clinical efficacy was demonstrated in the positive ZOTRIP pivotal trial results we reported this past February."

On February 13th, 2017, the Company announced positive results from the ZOTRIP pivotal efficacy study which 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. In this study the 3.8mg dose of M207 demonstrated a statistically significant benefit at the pre-specified primary endpoint (2 hours), and the secondary endpoint of pain freedom at 45 min after administration, with an effect that was sustainable for 48 hours post treatment. In addition, this dose of M207 also demonstrated statistically significant benefit in reversing patients' most bothersome symptom (photophobia, phonophobia or nausea and vomiting) at 2 hours post treatment.

"We are pleased and honored by the recognition of our propriety ADAM technology in the Pain Management Journal," stated John P. Walker, Zosano's Interim Chief Executive Officer. "We believe M207 addresses a clinical unmet need for patients struggling to find rapid pain relief for migraine episodes and look forward to making the additional preparations necessary to file for NDA approval in 2019."

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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