June 26, 2017

Zosano Pharma Announces Outcome of End of Phase 2 Meetings with FDA

- **Confirmation of previously announced design of Long-term Safety Study**
- **Recently completed ZOTRIP study acknowledged sufficient for NDA filing**
- **CMC development strategy confirmed adequate for registration**

FREMONT, Calif., June 26, 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, today announced receipt of final minutes from recent End of Phase 2 meetings with the U.S. Food and Drug Administration (FDA). The focus of this meeting was to confirm three key elements to the continued development of Zosano's lead program, M207 as an acute treatment for migraine:

- Confirmation of a single, positive Efficacy Study Sufficient for NDA filing — Zosano received confirmation that a single efficacy study, our recently completed ZOTRIP trial, is sufficient to support an NDA filing for M207. Final determination of whether sufficient efficacy has been achieved remains subject to an NDA submission and formal FDA review of the data from the ZOTRIP trial.

- Design of Long-term Safety Study — FDA confirmed the previously announced design of the Long-term Safety Study as sufficient to support an NDA filing for M207. The trial will evaluate the safety of repeat dosing of M207 in migraine patients, evaluating 150 patients to six months and 50 patients to a year. It is anticipated that patients will use M207 a minimum of twice per month. The primary emphasis will be on confirming skin tolerability during a year of dosing.

- Chemistry, Manufacturing and Controls — In a separate, concurrent communication, Zosano presented its proposed CMC development plan to the FDA. The FDA concurred that the development strategy, which conforms to relevant regulatory guidelines, appears adequate for registration of M207. CMC approval remains subject to NDA submission and FDA formal review and successful site inspections.

"We are pleased with the collaborative end-of-Phase 2 meetings with FDA that enabled us to receive detailed guidance regarding the further development of M207 and advancing towards an NDA filing," said Don Kellerman, Zosano's Vice President, Clinical Development and Medical Affairs. "This meeting represents the completion of another important milestone for M207, and we look forward to initiating our Long-term Safety Study in the third quarter of 2017, as previously announced."

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.

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. 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 gain 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. 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.

Zosano Contact:
John Walker
Interim Chief Executive Officer
510-745-1200

Investor Contact:
Jamien Jones
Blueprint Life Science Group
415-375-3340 x 5
jjones@bplifescience.com