

## ZOSANO PHARMA, INC. ANNOUNCES ZOSANO PHARMA, INC. COMPLETES POSITIVE END-OF-PHASE 2 MEETING WITH FDA REGARDING ZP- PTH PATCH FOR OSTEOPOROSIS

Fremont, Calif. – December 9, 2008 – Zosano Pharma, Inc., a privately held pharmaceutical company developing products using a novel transdermal delivery technology, today announced that it has completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding its ZP-PTH rapid delivery patch for the treatment of osteoporosis in women at high risk of fracture.

The meeting was an opportunity for Zosano to review with FDA requirements for the eventual NDA filing of ZP-PTH; specifically a phase 3 pivotal non-inferiority study to compare lumbar spine bone mineral density (BMD) at 12-months with ZP-PTH patch to FORTEO® teriparatide injection. Zosano reached agreement with the FDA on all key elements of the clinical trial, including the use of BMD as an appropriate surrogate end point to bridge to established fracture efficacy data for FORTEO. Zosano also received confirmation from FDA that a 505(b)(2) regulatory filing is appropriate for the ZP-PTH patch.

"This meeting was a critical milestone for advancing Zosano's lead product" stated Gail Schulze, Zosano's board chair and CEO. "We now have a clear path for future manufacturing, pre-clinical and clinical development, and are actively preparing for the start of the phase 3 study of the ZP-PTH patch. "

Zosano successfully completed a positive phase 2 multi-center, double-blind, multi-dose study demonstrating that daily administration of ZP-PTH for 24 weeks was well tolerated and resulted in a significant gain in BMD of the lumbar spine over placebo (p<0.001). The phase 2 study, which enrolled 165 post-menopausal women, demonstrated that the ZP-PTH 40 mcg patch provided a similar mean percent change from baseline in lumbar spine BMD compared to Forteo® 20 mcg injection (4.97% versus 3.55%, respectively).

ZP-PTH delivers PTH 1-34, teriparatide, a compound that has been proven to stimulate formation of new bone and reduce the risk of fractures. The ZP-PTH patch uses a unique transdermal technology being developed by Zosano as an alternative to daily injections.

## **About Osteoporosis**

Osteoporosis is a disease characterized by low bone mass and the deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures. While any bone can be affected, fractures of the hip, spine and wrist are especially common. Osteoporosis is a major public health issue, affecting 55% of people 50 years or older in the U.S.<sup>(1)</sup> Approximately 80% of those affected are women,<sup>(2)</sup> By 2025, experts predict that osteoporosis-related fractures will be responsible for an estimated \$25.3 billion in medical costs, <sup>(3)</sup> resulting in an economic burden comparable to other major chronic diseases.

## About Zosano Pharma, Inc.

Zosano Pharma, Inc. is a privately held pharmaceutical company developing products based on its novel transdermal delivery technology for a broad range of therapeutic indications. Its lead clinical program, the ZP-PTH rapid delivery patch for the treatment of osteoporosis, is being developed as an alternative to daily injections. Zosano's transdermal delivery technology is capable of delivering peptides, proteins, small molecules and vaccines by permeating the skin's outer layer and ensuring significant therapeutic effect. This proven proprietary technology offers several key benefits, including efficacy and safety comparable to approved injectables, needle-free delivery, a self-administered patch, rapid onset of action and room temperature storage. Zosano's transdermal delivery technology has been clinically tested in over 400 patients with four different peptides and a vaccine. Zosano aims to develop products both independently and through strategic licensing and codevelopment arrangements. Founded in 2006 as an ALZA Corporation spin-out led by Nomura Phase4 Ventures, Zosano is funded by New Enterprise Associates, Nomura Phase4 Ventures, HBM BioVentures and ProQuest Investments. For more information, please visit <a href="https://www.zosanopharma.com">www.zosanopharma.com</a>.

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