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## **Zelos Therapeutics Initiates Dosing in a Phase 1 Clinical Study of Nasal Spray Teriparatide**

**-7 day study will provide an initial comparison with Eli Lilly's Forteo®-**

West Conshohocken, PA – (January 28, 2010) – Zelos Therapeutics, Inc. has initiated dosing in a seven day clinical study of a nasal spray formulation of ZT-034 (teriparatide) that is being developed in collaboration with development partner Aegis Therapeutics, LLC. Nasal spray ZT-034 is being developed as an alternative to Eli Lilly and Company's Forteo (teriparatide [rDNA origin]) which generated approximately \$800M in annual sales in 2009 for the treatment of osteoporosis and is administered by daily injection. Non-injectable formulations such as nasal spray ZT-034 could expand the market for parathyroid hormone (PTH) analogs to considerably more than \$1 billion. The study design will include a Forteo treatment arm to provide an initial comparison with the marketed product.

“PTH analogs such as teriparatide are an important but underutilized therapeutic option for osteoporotic patients at high risk of fracture,” stated Dr. Brian MacDonald, CEO of Zelos Therapeutics. “We believe that formulation of teriparatide as a nasal spray with comparable efficacy and safety to Forteo represents a simple, convenient approach to dosing that will make PTH therapy a better option for many more patients.”

Nasal spray ZT-034 is formulated with Aegis Therapeutics' proprietary agent Intravail® to create a stable solution of teriparatide and enhance absorption of the peptide across the nasal mucosal surface. “We are pleased to be working with Zelos on this important application of our drug delivery technology,” commented Dr. Ed Maggio, CEO of Aegis Therapeutics. “Intravail® has produced dramatic increases in intranasal bioavailability for many peptides and other difficult to deliver therapeutics, in a simple, well tolerated method of delivering peptides without an injection.”



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Zelos Therapeutics plans to develop nasal spray ZT-034 under the 505(b)(2) regulatory pathway that was included in the Federal Food, Drug and Cosmetic Act by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). This regulatory approach permits companies to obtain FDA approval of new drug applications (NDAs) by relying, in part, on the agency's findings of safety and/or efficacy for a previously approved drug. Section 505(b)(2) is intended to encourage innovation in drug development by permitting certain modifications of approved drugs without requiring duplicative studies to demonstrate what is already known about a previously-approved product.

### **About Zelos Therapeutics, Inc.**

Zelos Therapeutics specializes in the development of innovative treatments for bone disorders and related indications in large, underserved markets. Led by an experienced team of biopharmaceutical executives and funded by leading health care investors, Zelos Therapeutics is advancing a portfolio of product opportunities into late stage clinical development. For more information about Zelos Therapeutics, please visit the company's website at [www.zelostherapeutics.com](http://www.zelostherapeutics.com).

### **About Aegis Therapeutics, LLC**

Aegis Therapeutics LLC is a drug delivery technology company commercializing its patented drug delivery and drug formulation technologies through product-specific licenses to pharmaceutical and biotechnology companies including F. Hoffmann-La Roche, Dr. Reddy's Laboratories, Nerveda, and Zelos Therapeutics, in addition to a number of undisclosed pharmaceutical and biotechnology partners. Our patented Intravail<sup>®</sup> drug delivery technology enables the non-invasive delivery of a broad range of protein, peptide and non-peptide macromolecular and small molecule therapeutics via the intranasal administration route with exceptionally high and unmatched bioavailability that can currently only be achieved by injection. Intravail<sup>®</sup> has also been successfully applied to buccal, oral, and rectal administration of both small molecule and peptidic drugs. Our patented ProTek<sup>®</sup> technology allows creation of proprietary, easily manufacturable, and stable aqueous or lyophilized dosage forms that maintain the integrity and physiological activity of many protein and peptide therapeutics. ProTek<sup>®</sup> technology is applicable to injectable, intranasal, and other dosage forms. For more information about Aegis, please visit the Aegis website at: [www.aegisthera.com](http://www.aegisthera.com).

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