

September 21, 2006

Zelos and Nektar Announce Start of Phase 1 Trial of Inhaled Ostabolin-C(TM) for Osteoporosis

WEST CONSHOHOCKEN, Pa. & OTTAWA & SAN CARLOS, Calif., Sep 21, 2006 (BUSINESS WIRE) -- Zelos Therapeutics, Inc., a private biopharmaceutical company focused on developing novel therapies for patients suffering from osteoporosis, and Nektar Therapeutics (Nasdaq: NKTR) today announced the initiation of a Phase 1 clinical trial of an inhaled powder formulation of Zelos' proprietary parathyroid hormone Ostabolin-C(TM) (cyclic PTH-(1-31)). Nektar and Zelos entered into a collaboration to develop an inhaleable powder form of Ostabolin-C in January 2005.

"Ostabolin-C is a powerful new bone formation agent that we believe will emerge as a best-in-class PTH for the treatment of osteoporosis. A key to expanding the market for bone formation therapies will be the development of convenient non-injectable delivery alternatives that can improve both patient compliance and thus, treatment outcomes in osteoporosis," commented Brian MacDonald, MB, ChB, PhD, chief executive officer of Zelos. "Our strategy is to evaluate several delivery options for Ostabolin-C and we are pleased to advance this promising inhaled version of Ostabolin-C into the clinic with our partner Nektar."

"This product has the potential to address the need for a more convenient, patient-friendly and much-needed therapy option for osteoporosis patients," said David Johnston, senior vice president of research and development at Nektar. "Inhaled Ostabolin-C uses Nektar's small, pocket-sized inhaler to deliver a peptide and it is designed to provide a portable and easy-to-use solution for patients."

About the Study

The Phase 1 trial is a single-center randomized, double blind, placebo-controlled, escalating-dose study that will enroll up to 56 healthy postmenopausal women. The study will evaluate 28 days of dosing. The dry powder formulation of Ostabolin-C will be administered using Nektar's convenient, pocket-sized dry powder inhaler. The primary study endpoints are the safety and tolerability of single and repeated doses of inhaled Ostabolin-C. In addition, the study will evaluate the pharmacokinetics and pharmacodynamics of inhaled Ostabolin-C, as well as the effect of inhaled Ostabolin-C on serum markers of bone formation and resorption. The Phase 1 trial includes a sub-study to compare the pharmacokinetic characteristics of a single dose of Ostabolin-C given via a subcutaneous (SC) injection and a single dose of inhaled Ostabolin-C.

About Ostabolin-C

Ostabolin-C, a cyclic 1-31 amino acid analog of parathyroid hormone (PTH), is a bone formation agent designed to improve upon the safety and efficacy of current therapies in the large and rapidly growing osteoporosis market. Preclinical and Phase 1 studies have shown that Ostabolin-C stimulates significant bone formation with little to no stimulation of bone resorption. Due to the minimized bone resorption, Ostabolin-C demonstrates a reduced potential to cause hypocalcaemia, a common side effect of current PTH therapies. With this profile, Ostabolin-C may become a best-in-class compound in the growing PTH market and a leading therapy in the treatment of osteoporosis. Zelos is currently conducting Phase 2 clinical studies with Ostabolin-C as a once-daily, self-administered subcutaneous injection.

To address the need for more convenient and patient-friendly non-injectable delivery, Nektar and Zelos are partnered for the development of an inhaled formulation of Ostabolin-C. Nektar's Advanced Pulmonary Technology is designed to provide an integrated inhalation system that disperses fine, dry, respirable powders in a reproducible fashion for optimal systemic delivery.

About Nektar Advanced Pulmonary Technology

Nektar Advanced Pulmonary Technology uses innovative molecular formulations and novel delivery devices designed for easeof-use to improve or enable administration of medicines to and through the lungs for both lung diseases and systemic conditions. The company has two proprietary pulmonary anti-infective products currently in clinical development and four additional pulmonary products in the clinic with various partners. Exubera(R) (insulin human (rDNA origin)) Inhalation Powder, which has been approved in the U.S., European Union, Brazil and Mexico, is the most advanced product using Nektar Advanced Pulmonary Technology and is a result of a developmental collaboration between Pfizer and Nektar. Zelos Therapeutics, Inc. is a biopharmaceutical company developing novel, best-in-class therapies to address the unmet medical needs of patients suffering from osteoporosis. The Company is in late-stage clinical development with Ostabolin-C, a bone formation PTH analog designed to improve upon the safety and efficacy of current therapies in the large and rapidly growing osteoporosis market.

Zelos Therapeutics is led by a group of seasoned executives, and is based in West Conshohocken, Pennsylvania and Ottawa, Ontario. To address the need for a more convenient PTH therapy for osteoporosis, the Company is collaborating with Nektar Therapeutics for the development of an inhaled formulation of Ostabolin-C. More information is available at www.zelostherapeutics.com.

About Nektar

Nektar Therapeutics is a biopharmaceutical company that develops and enables differentiated therapeutics with its industryleading drug delivery technologies, expertise and manufacturing capabilities. Nektar technology and know-how have enabled nine approved products for partners, which include the world's leading pharmaceutical and biotechnology companies. Nektar also develops its own products by applying its drug delivery technologies and expertise to existing medicines to enhance performance, such as improving efficacy, safety and compliance.

This press release contains forward looking statements regarding the potential for a more patient-friendly delivery method for Ostabolin-C, patient compliance benefits, and the value and benefits of Nektar Advanced Pulmonary Technology in combination with Ostabolin-C. These forward looking statements involve uncertainties and other risks, including but not limited to (i) the substantial risks of early stage clinical trial programs, (ii) the uncertain regulatory process for potential new products, (iii) the commercial feasibility of early stage development products, (iv) the efficacy and ease of patient use of an inhaleable form of Ostabolin-C in comparison to other delivery methods, and (v) the ability of collaborative partners to successfully obtain regulatory approvals and their ability to market and sell new products if approved. Other important risks and uncertainties are detailed in the company's reports and other filings with the SEC, including its most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and Current Reports on Form 8-K. Actual results could differ materially from the forward-looking statements, whether as a result of new information, future events or otherwise.

Ostabolin-C is a trademark of Zelos Therapeutics, Inc.

Exubera is a registered trademark of Pfizer Inc

SOURCE: Zelos Therapeutics, Inc. and Nektar Therapeutics

For Zelos: Brian MacDonald, 610-825-4549 or MacDougall Biomedical Communications Kari Watson, 508-647-0209 kwatson@macbiocom.com or For Nektar: Jennifer Ruddock, 650-631-4954 or Joyce Strand, 650-631-3138

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