



Elixir Pharmaceuticals Initiates Final Phase III Clinical Study Prior to NDA

- Mitiglinide May Offer New Treatment Option for Type 2 Diabetes -

CAMBRIDGE, Mass. -- Aug. 20, 2007—Elixir Pharmaceuticals, Inc., announced today the initiation of its final, pivotal phase III clinical study of mitiglinide for the treatment of patients with type 2 diabetes. The phase III clinical study is expected to be completed in mid-2008, with data available shortly thereafter. The results from this study will supplement the existing clinical database (phases I-III) of nearly 4,000 patients to form the basis of the Company's anticipated New Drug Application submission to the FDA.

In previous clinical studies, mitiglinide therapy has been shown to significantly lower patients' levels of HbA1c (hemoglobin A1c), the standard measure of glucose control. In addition, mitiglinide has been shown to improve the body's own ability to produce insulin in a glucose-dependent manner at meal time, mimicking the natural glucose response by producing a rapid and brief burst of insulin when glucose levels begin to elevate.

"There continues to be a tremendous unmet medical need in the U.S. for therapeutics that can be used alone or in combination with other drugs to provide patients with type 2 diabetes with more complete glucose control throughout the day," commented John Whisnant, M.D., the Chairman of Elixir's Clinical Advisory Board. "If approved, mitiglinide could offer a new, versatile treatment option for patients who are not getting adequate glucose control with metformin therapy alone."

The randomized, double-blind, placebo-controlled clinical study is expected to enroll over 300 patients, across more than 50 sites in the U.S. The study is designed to evaluate the efficacy and safety of mitiglinide in combination with metformin in patients whose blood sugar is not adequately controlled by metformin alone. At enrollment, metformin patients are randomized to receive either placebo or mitiglinide. The primary objective of the study is to demonstrate the superiority of mitiglinide (compared to placebo) as measured by improvement in HbA1c from baseline after 24 weeks of treatment. The secondary objective of the study is to evaluate mitiglinide and metformin combination therapy compared to metformin monotherapy as measured by fasting plasma glucose (FPG) and 2-hour post-meal glucose levels. Patient recruitment for the study is designed to include U.S. minority populations.

Elixir recently published results from two completed mitiglinide clinical studies at the American Diabetes Association annual meeting, the first study demonstrating that type 2 diabetes patients can be treated safely and effectively with mitiglinide as first-line monotherapy. The second study demonstrated mitiglinide, when added to metformin therapy, provided additional reductions in HbA1c (versus metformin alone) and offers

patients more complete glucose management through the complementary mechanisms of the two drugs.

"The initiation of this final phase III mitiglinide study is an important event for Elixir. It represents the final data component needed for our planned New Drug Application, which we intend to submit to the FDA in 2009," stated William K. Heiden, Elixir's President and Chief Executive Officer. "The type 2 diabetes market in the U.S. continues to grow and has resulted in significant opportunities for the development of innovative drugs, including mitiglinide, a treatment we believe will offer patients a best-in-class therapy to control blood glucose.

"Overall, Elixir is in a unique position, with an advanced product in the last stage of clinical testing, as well as a broad development pipeline. We have a number of exciting, internally generated programs focused on diabetes and obesity. These programs include ghrelin antagonism for the treatment of a broad range of metabolic diseases and modulators of SIRT enzymes, which, like ghrelin, play a key role in the regulation of metabolic function."

About Type 2 Diabetes

Type 2 diabetes is a serious and debilitating disease, affecting more than 20 million Americans in the U.S. alone (30% of whom are estimated to be undiagnosed). While there has been significant progress in the treatment of type 2 diabetes in the last decade, there is still an enormous unmet medical need worldwide. Type 2 diabetes, which can be diagnosed at any age, results from a reduction in the body's ability to produce insulin, which controls blood sugars, or the body's cells become resistant to insulin. Type 2 diabetes increases the risk for many serious complications, particularly heart disease, blindness, nerve damage and kidney damage, all of which can be reduced by strictly controlling the level of blood sugar. Type 2 diabetes is also the leading cause of amputations.

While type 2 diabetes is diagnosed in all U.S. populations, African Americans, Latinos, Native Americans and Asian Americans/Pacific Islanders are at a higher risk for the disease, as are the elderly population. Minorities have not only a higher prevalence of diabetes than Caucasians(1), but it has also been reported that some minorities have higher rates of diabetes-related complications and death.(2)

About Mitiglinide

Mitiglinide is a member of the meglitinide class of compounds; two currently marketed products in this class generated nearly \$300 million in sales in the U.S. in 2006. Marketed by Kissei in Japan since 2004, mitiglinide's efficacy and safety in type 2 diabetes is supported by three years of in-market use in Japan. Mitiglinide has been studied extensively in human clinical studies in the U.S., Europe, Australia, and Asia. Clinical trial results, including more than 1,500 patients treated in phase III trials, have demonstrated an excellent safety and efficacy profile for mitiglinide.

Results from several clinical studies demonstrate mitiglinide effectively reduces HbA1c levels (a standard means of assessing chronic elevated blood glucose levels) in type 2 diabetes patients. Mitiglinide lowers blood glucose by stimulating the release of insulin from the pancreas. This insulin release is glucose-dependent and helps control the

elevated post-meal glucose levels seen in type 2 diabetic patients. Epidemiological studies indicate uncontrolled post-meal glucose surges are associated with negative long-term health outcomes in diabetics, such as increased cardiovascular morbidity.

In March 2006, Elixir in-licensed North and South American rights to mitiglinide. Under the terms of the licensing agreement with Kissei, Elixir has the right to develop and commercialize mitiglinide and any future product combinations, in the U.S., Canada and Latin America.

About Elixir Pharmaceuticals

Elixir is a Cambridge, MA-based biopharmaceutical company focused on the discovery, development and commercialization of drugs to treat and prevent metabolic disease.

In addition to mitiglinide, Elixir has a broad program focused on manipulating ghrelin, a naturally occurring hormone that plays a unique and central role in overall metabolic regulation. The Company is advancing a proprietary, small molecule antagonist designed to bind to the human ghrelin receptor. Elixir has filed broad intellectual property protection on all aspects of the ghrelin antagonist program, including composition of matter protection covering five novel compound classes and their therapeutic uses. The Company plans to advance the first ghrelin inhibitor into clinical testing in 2008.

In addition to its ghrelin antagonist program, the Company has leveraged its knowledge of ghrelin biology and pharmacology in the development of small molecule ghrelin agonists. The Company's lead clinical candidate, EX-1314 binds selectively to the ghrelin receptor and mimics the body's naturally occurring ghrelin. In doing so, this novel, orally available agent is capable of stimulating appetite, gastric motility and the release of growth hormone. Elixir is currently in IND-enabling studies with EX-1314 targeting a variety of therapeutic indications.

Elixir also has developed expertise and a broad IP portfolio of more than 20 patents and patent applications related to the Sirtuin class of proteins, including small molecular weight SIRT1 activators and inhibitors. Additionally, Elixir actively is pursuing drug discovery efforts focused on other key targets, such as AMP-activated kinase (AMPK), which Elixir has shown to be implicated in the regulation of aging and metabolism in a variety of organisms.

More information about Elixir is available at
<http://www.elixirpharm.com/>

(1) Mokdad AH, Ford ES, Bowman BA, et al. Diabetes trends in the U.S.: 1990-1998. *Diabetes Care* 2000;23(9):1278-83

(2) Carter JS, Pugh JA, Monterrosa A. Non-insulin-dependent diabetes mellitus in minorities in the United States. *Ann Intern Med* 1996;125(3):221-32. (AHRQ Grant HS07397)

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