



Elixir Pharmaceuticals' Phase III Trial of Metformin-Mitiglinide Combination Therapy Demonstrates Significant Reductions in HbA1c (Blood Glucose) Levels Compared to Type 2 Diabetes Patients Not Well-Controlled on Metformin Alone

- Company to Submit NDA for Lead Product, Metgluna™ -

Cambridge, MA – November 19, 2008 – Elixir Pharmaceuticals, Inc., announced today positive results from a pivotal phase III clinical study of the Company's oral formulation of mitiglinide administered in combination with metformin for the treatment of patients with type 2 diabetes. The study achieved statistical and clinical significance in its primary efficacy endpoint. Patients receiving the combination of twice-daily mitiglinide and metformin experienced a statistically significant additional reduction in hemoglobin A1c (HbA1c) levels compared to patients receiving metformin alone. HbA1c is a measure of average blood sugar over time and takes into account the baseline level of sugar (fasting plasma glucose) and the rises that occur after a meal (post-meal glucose). The final results from this study will be submitted for presentation to an upcoming national scientific meeting.

"These positive results from our study provide additional clinical evidence supporting the benefits of Metgluna therapy in the treatment of type 2 diabetes. Metgluna, a one-tablet, fixed combination therapy taken twice daily could allow for a simple, effective and safe transition of patients on twice-daily metformin who need to attain better glycemic control," stated Paul Martha, M.D., Elixir's Chief Medical Officer and SVP, Clinical Development and Regulatory Affairs. "Metformin has been safely used in clinical practice for more than 50 years, while mitiglinide has been safely prescribed to hundreds of thousands patients worldwide. The complementary mechanisms of these two products make them an ideal combination product. Metformin effectively lowers blood glucose levels throughout the day by increasing insulin sensitivity, and mitiglinide specifically works to reduce the meal-time glucose elevations experienced by most diabetic patients. These two drugs in a convenient fixed combination tablet will offer a superior therapeutic option for physicians and their diabetic patients compared to metformin alone."

In addition to meeting its efficacy endpoint, Elixir's phase III study demonstrated that the combination of metformin plus mitiglinide is a very safe therapy. The safety findings of this phase III trial corroborated data from previous studies in more than 4,000 patients, demonstrating an excellent safety profile with no signals of serious adverse events related to mitiglinide. This is particularly important because the need for safe new therapies which provide additional benefit to patients whose diabetes is not adequately controlled by metformin alone has become particularly acute recently. Patients and their physicians increasingly recognize that some currently available type 2 diabetes drugs

cause unacceptable increased risk of serious cardiovascular events, major hypoglycemia, bone fracture, weight gain and edema (water retention).

The results from the phase III study, along with data from earlier safety and efficacy studies, will support the submission of a new drug application (NDA) to the U.S. FDA for Metgluna™, Elixir's lead product, in 2009. Metgluna is a fixed combination tablet of metformin plus mitiglinide offering convenient twice-daily dosing.

"The results from this trial demonstrate that Metgluna is a safe and effective next step for metformin patients who would need additional glycemic control," commented James R. Gavin III, M.D., Ph.D., Chairman of Elixir's Diabetes Advisory Board, Clinical Professor of Medicine at Emory University and past president of the American Diabetes Association (ADA). "The clinical need is compelling. There are nearly six million type 2 diabetes patients in the United States who are treated with metformin. Of these patients, most would eventually require added therapies in order to achieve sufficient reductions in HbA1c to meet current clinical guidelines."

Elixir's phase III study was a 24-week, randomized, double-blind, placebo-controlled trial enrolling more than 350 patients at more than 60 sites in the United States. All patients entered into the trial were deemed to be inadequately controlled (HbA1c above goal) on a stable dose of metformin alone. Patients were randomized to initially receive 10 mg twice daily (or three times daily) of mitiglinide or placebo in addition to their metformin therapy. Patients were titrated for efficacy, using mitiglinide doses of 10, 20 or 40 mg while continuing on their previous metformin dose.

About Type 2 Diabetes

Type 2 diabetes is a chronic metabolic disorder characterized by high blood sugar caused by defective insulin secretion, resistance to insulin action or a combination of both. It is a serious and debilitating disease, affecting more than 23 million Americans in the U.S. alone, 25% 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.

Approximately half of people diagnosed with type 2 diabetes have not achieved adequate blood sugar level control, as measured by HbA1c. The American Diabetes Association recommends that patients with type 2 diabetes achieve a target HbA1c level of less than 7%. 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 tightly controlling the level of blood sugar.

About Metgluna™ and Mitiglinide

For patients with type 2 diabetes not well controlled on metformin alone, Metgluna will provide additional HbA1c reduction through comprehensive glycemic control via two complementary mechanisms of action. Metgluna is a fixed combination tablet of metformin, which helps control fasting plasma glucose by improving insulin sensitivity, and mitiglinide, a product that mimics the body's natural response to glucose by producing a rapid and brief burst of insulin when glucose levels begin to rise to provide for better control of post-meal glucose surges.

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 studies, have demonstrated an excellent safety and efficacy profile for mitiglinide as monotherapy and in combination with metformin. Elixir's recently completed phase III trial, enrolling more than 350 patients across more than 60 sites in the U.S., demonstrated that the Company's formulation of mitiglinide in combination with metformin safely and effectively reduced HbA1c levels versus patients on metformin alone.

Elixir in-licensed North and South American rights to mitiglinide from Kissei Pharmaceuticals. Under the terms of the licensing agreement, 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 pharmaceutical company focused on the discovery, development and commercialization of novel pharmaceuticals for the treatment of metabolic diseases such as diabetes and obesity. The Company's scientific founders identified that modulation of specific genes can slow the aging process and increase longevity. Elixir is developing small molecule drugs that mimic these longevity responses, and these drugs will be used to treat a range of age-related diseases, including the major metabolic diseases.

In addition to its late-stage product development program, the Company is developing an oral ghrelin antagonist for the treatment of metabolic disease. Elixir is also developing EX-1314, an oral drug being developed for the treatment of type 1 diabetic gastroparesis. Further, the Company's SIRT product development program is exemplary of how Elixir continues to use its understanding of the pathways which slow the aging process to identify interesting targets for the development of drugs to treat metabolic disease.

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