



Elixir Pharmaceuticals Announces Clinical Data at American Diabetes Association Conference Highlighting Ability of Glufast® to Maintain Glycemic Control in Patients with Type 2 Diabetes

Glufast® Shows Activity as Monotherapy and in Combination with Metformin

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Elixir Pharmaceuticals, Inc., announced today the publication of clinical data highlighting the ability of Glufast® (mitiglinide calcium hydrate) monotherapy, or combination therapy with metformin, to manage glucose surges before and after meals. The data were published in the Abstract Book for the American Diabetes Association 67th Annual Scientific Sessions in Chicago, Illinois. Glufast is an insulin secretagogue that lowers postprandial (post-meal) glucose levels by improving the body's own ability to produce insulin. Marketed in Japan since 2004, Glufast has an extensive clinical package that demonstrates the product's ability to effectively and safely treat Type 2 diabetes.

"The publication of these data provide compelling confirmatory evidence that Glufast can control and reduce post-meal glucose, and in combination with metformin may offer complete glucose management, both before and after meals," commented William K. Heiden, Elixir's President and Chief Executive Officer. "These studies and other similar data led us to in-license Glufast, which we expect to be our first commercial product. This drug has been well received outside of the U.S., and its efficacy and safety are well documented. As endocrinologists and general practitioners have different prescribing habits and dosing requirements, we will be pursuing Glufast both as a single agent and in combination with metformin to meet their needs. We are working towards initiating a final Phase III clinical study of Glufast in the U.S. this year."

The first study detailed findings from a randomized, double-blind trial comparing Glufast to acarbose in 369 elderly patients (at least 65 years of age) with Type 2 diabetes mellitus (T2DM). The patients were randomized to receive either Glufast or acarbose and were stratified by country and prior oral hyperglycemic agent (OHA) treatment. More than 80 percent of patients enrolled had been receiving one OHA treatment prior to their enrollment in this study, but their baseline glycemic control was insufficient. Institute Servier sponsored the study, which was conducted at major diabetes and gerontology centers in the UK, Australia, France, Poland, Russia, Brazil, and Mexico.

The results of the study demonstrated glycemic control was managed better by Glufast than by acarbose. After six months, HbA1c levels (a standard means of assessing chronic elevated blood glucose levels) were 7.43 +/- 1.03 in patients receiving Glufast and 7.75 +/- 1.47 in patients receiving acarbose (ITT, $p < 0.001$).

Major hypoglycemia events did not occur in either arm. Minor hypoglycemic events were reported in 7.6 percent of patients receiving Glufast®. In patients receiving acarbose, 22 percent withdrew due to adverse effect withdrawals, primarily gastrointestinal effects. In the Glufast arm, 10 percent of patients withdrew due to adverse effects, 3.3 percent of which were due to hypoglycemia.

The second study examined the potential efficacy of adding Glufast® to metformin for the treatment of patients with T2DM. Metformin has become the standard for initiation of OHA therapy after diet and exercise fail to control HbA1c levels. The Institute Servier-sponsored trial,

which took place in Australia and New Zealand, enrolled 324 T2DM patients who had received metformin for a minimum of four months. The patients then were assigned randomly to continue metformin, receive metformin with titrated doses of Glufast, or to switch to Glufast alone. Baseline glycemic control was inadequate in all groups. The primary endpoint of this trial was continued or improved control of HbA1c.

The results of the study demonstrated glycemic control was improved by the combination of Glufast and metformin with HbA1c levels at 7 months being 7.13 ± 0.82 compared with 7.70 ± 0.86 in the metformin alone arm. Major hypoglycemia did not occur in either arm. Minor hypoglycemia was reported in 14.7 percent of patients receiving both drugs compared with 1.9 percent of patients on metformin alone but did not cause excessive adverse effect withdrawals from the study. The total percentage of patients who discontinued for adverse effects was 5.5 percent on two drugs compared with 2.9 percent for patients only receiving metformin.

About Glufast

Glufast, an insulin secretagogue with a rapid onset and short duration of action, lowers post-meal glucose levels by improving the body's own ability to produce insulin. Clinical data have shown HbA1c levels (a standard means of assessing chronic elevated blood glucose levels) are decreased when Glufast is used to reduce post-meal glucose surges. Epidemiological studies have demonstrated uncontrolled post-meal glucose surges are associated with negative long-term health outcomes in diabetics.

Glufast is a member of the mitiglinide class of compounds; two currently marketed products in this class are believed to have generated over \$300 million in sales in the U.S. in 2006. Glufast has been studied extensively in human clinical trials in the U.S., Europe, Australia, and Asia. Clinical results from more than 1,500 treated patients, including several years of in-market use in Japan, support Glufast's safety and effectiveness and will be used in Elixir's registration efforts in its licensed territories.

Under the terms of the licensing agreement with Kissei, Elixir will have the right to develop and commercialize Glufast, as well as future products that combine Glufast with other compounds, in the U.S., Canada, and Latin America. For these rights, Elixir will make payments to Kissei based on predetermined milestones, as well as pay a royalty to Kissei on net sales. Additional financial terms were not disclosed.

About Type 2 Diabetes

Type 2 diabetes is a serious and debilitating disease, affecting 14 million patients in the United States alone. While there has been significant progress in the treatment of Type 2 diabetes, there is still an enormous unmet medical need worldwide.

About Elixir Pharmaceuticals

Elixir is a Cambridge, MA-based biopharmaceutical company focused on developing and commercializing drugs to treat and prevent metabolic disease, prevent age-related diseases, ultimately extending the quality and length of human life.

In addition to the Glufast program, the Company has leveraged its knowledge of ghrelin biology and pharmacology and is advancing both ghrelin antagonists and agonists.

The Company's ghrelin antagonist, EX-1350, is a proprietary, small molecule designed to bind to the human ghrelin receptor. Elixir has demonstrated EX-1350 reduces body weight by 10 percent at 28-56 days without significant decreases in food intake in an animal model made insulin resistant and obese after three months on a 60 percent fat diet. The majority of the weight loss is

observed in white adipose tissue, with sparing of skeletal muscle. Furthermore, glucose surge and disposal was found to be improved significantly in EX-1350-treated mice compared to vehicle, and the insulin required to dispose of the glucose was reduced dramatically, indicating improved insulin sensitivity.

In April 2005, Elixir licensed a small molecule ghrelin agonist (designated EX-1314) from Bristol-Myers Squibb Company. 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 twenty patents and patent applications related to the Sirtuin class of proteins, including small molecular weight SIRT1 activators and inhibitors. The Company's own R&D efforts and those of its numerous research partners utilizing modulators of SIRT1 (a human sirtuin) have extended the SIRT knowledge base significantly in recent years. Elixir is also actively 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/>

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