

Elixir Pharmaceuticals Announces Ghrelin Agonist Data Presentation at the Endocrine Society Annual Meeting

First Presentation of Data Demonstrating Increases in Gastrointestinal Motility by an Orally Active Ghrelin Agonist

ENDO 2008

CAMBRIDGE, Mass.--([BUSINESS WIRE](#))-- Elixir Pharmaceuticals, Inc., today announced that results from in-vivo preclinical studies with the Company's ghrelin agonist, EX-1314, were presented at the annual meeting of the Endocrine Society. EX-1314 is expected to enter human clinical testing this year. This new compound has been the subject of extensive preclinical development, and these new data provide the first demonstrations that an orally active, small molecule ghrelin agonist can enhance gastrointestinal motility. Elixir will develop EX-1314 as a treatment for gastrointestinal disorders, which include gastroparesis, opioid-induced bowel dysfunction and cancer cachexia. These newest findings were presented in a poster session, titled "Enhanced gastrointestinal motility with EX-1314, an orally active small molecule ghrelin receptor agonist," at ENDO 2008, the annual meeting of the Endocrine Society being held in San Francisco. Authors of the study included Soratree Charoenthongtrakul and Brad Geddes, both of Elixir Pharmaceuticals.

The findings demonstrated that Elixir's oral ghrelin agonist EX-1314 was as potent and efficacious as the naturally occurring ghrelin peptide (delivered via injection) in stimulating gastric (stomach) emptying, intestinal transit and fecal output, compared to placebo. No effects were seen for either ghrelin or EX-1314 administered to "knockout" mice lacking the ghrelin receptor, indicating that the beneficial effects of increased motility are mediated by the ghrelin receptor. In addition, Elixir has demonstrated in a separate animal model that oral treatment with EX-1314 normalized gastrointestinal function in a model of opioid-induced bowel dysfunction compared to placebo. It has previously been demonstrated that morphine injections slow gastrointestinal transit in mammals, including humans. In these animal studies EX-1314 was able to reverse this effect and restore gastrointestinal motility.

Dr. Peter S. DiStefano, Chief Scientific Officer of Elixir Pharmaceuticals and an author on the poster, stated, "The ghrelin peptide is the standard for research in ghrelin agonism, and multiple studies have demonstrated ghrelin's profound effects on gastrointestinal motility. I believe that today's reported findings represent the first in-vivo demonstration that an orally active small molecule agonist of ghrelin can have an effect similar to ghrelin in gastrointestinal motility. Furthermore, we have confirmed the putative mechanism of action of EX-1314 via the ghrelin receptor, since our compound showed no activity in mice lacking the ghrelin receptor. We are very excited about the potential clinical utility of EX-1314 in areas where there is currently significant unmet medical need, and we look forward to developing this compound through human clinical trials beginning this year."

About Ghrelin

Ghrelin is a naturally occurring hormone secreted by the stomach, which acts primarily at the level of the hypothalamus in the brain. A key metabolic regulator, ghrelin plays a significant role in the regulation of a broad range of metabolic functions. It has been shown to stimulate appetite, increase food consumption, and increase gastrointestinal motility. Ghrelin also plays a central role in the metabolism and storage of energy.

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 oral ghrelin agonists and antagonists, the Company has two late-stage products (Metgluna(TM) and Glinsuna(TM)) for the treatment of type 2 diabetes in a final phase III trial in the U.S., with NDA filing expected in 2009. 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.

About Metgluna and Glinsuna

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.

The companion product Glinsuna 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 as monotherapy or in combination with metformin. An ongoing phase III clinical study enrolled more than 300 patients across 60 sites in the U.S. and was designed to evaluate the efficacy and safety of Glinsuna in combination with metformin in patients whose blood sugar is not adequately controlled by 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's Sirtuin Development Program

Building upon the Company's knowledge of the regulation of aging and metabolism, Elixir Pharmaceuticals has developed a leadership position in the field of sirtuins, or SIRT, a class of seven naturally occurring human enzymes, known to affect the storage and use of energy in cells. Elixir Pharmaceuticals believes that sirtuin modulators, compounds which increase or decrease the activity or the amount of sirtuin enzymes, may have potential clinical utility in numerous, large pharmaceutical markets with unmet medical needs, such as metabolic disease, cancer and neurodegenerative diseases. Elixir Pharmaceuticals has an extensive intellectual property estate which includes know-how and patents (pending and issued) related to screening, assays, mechanism/pathway knowledge, and chemical composition of matter and utility claims for sirtuin modulators.

About Elixir's Ghrelin Development Programs

Using structure-assisted drug design, a method of creating chemical compounds based on an understanding of the configuration of the human ghrelin receptor, Elixir has internally discovered and developed a series of potent, small molecule antagonist compounds that block the ghrelin receptor. Oral administration of these compounds in animal models of diet-induced obesity and early diabetes resulted in similarly favorable metabolic effects to those seen in knockout models with respect to improved blood glucose levels, insulin resistance, HbA1c, triglycerides, total cholesterol, liver fat, body weight and white fat when compared to placebo. Elixir is completing selection of a clinical candidate and expects to file an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) early in 2009, initiating a phase I clinical trial shortly thereafter.

In addition, the Company has submitted an IND to the FDA for EX-1314, Elixir's novel oral ghrelin agonist. EX-1314 is being developed for the treatment of chronic gastrointestinal disorders, including gastroparesis, a disorder in which the stomach takes too long to empty its contents. EX-1314 will be developed initially for gastroparesis in patients with type 1 diabetes, which is the most common systemic cause of gastroparesis.

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