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Elixir Pharmaceuticals Establishes National Diabetes Advisory Board

CAMBRIDGE, Mass.--([BUSINESS WIRE](#))--Elixir Pharmaceuticals, Inc., announced today the formation of its U.S. Diabetes Advisory Board to provide independent scientific and clinical advice regarding the Company's product candidates in phase III development, Glinsuna™ (mitiglinide) and Metgluna™ (mitiglinide plus metformin), for the treatment of type 2 diabetes, as well as to provide input on other Elixir product candidates in development to treat metabolic diseases. James R. Gavin III, M.D., Ph.D., Clinical Professor of Medicine at Emory University and past president of the American Diabetes Association (ADA), has been named chair of the Elixir Diabetes Advisory Board. Members of the advisory board also include: Lawrence Blonde, M.D., Rhoda H. Cobin, M.D., John E. Gerich, M.D., Paul S. Jellinger, M.D., John L. Leahy, M.D. and Janet B. McGill, M.D.

"Elixir Pharmaceuticals is dedicated to the discovery, development and commercialization of pharmaceuticals to treat metabolic disease. We are honored to name seven of the country's leading diabetologists to our Diabetes Advisory Board," commented Paul M. Martha, M.D., Elixir's Chief Medical Officer and Senior Vice President, Clinical Development and Regulatory Affairs. "Each of our advisory board members has demonstrated a career-long dedication to improving the quality of care and to advancing new treatment options for patients with diabetes. Their expertise will provide valuable input to Elixir across our portfolio of products in development to treat metabolic disease."

Members of Elixir's Diabetes Advisory Board

Lawrence Blonde, M.D., is Director of the Ochsner Health System Diabetes Clinical Research Unit in New Orleans. He is also Chair of the Steering Committee of the National Diabetes Education Program (NDEP), a partnership of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention and more than 200 public and private organizations. Dr. Blonde received his M.D. degree from Albany Medical College.

Rhoda H. Cobin, M.D., MACE, is a Clinical Professor of Medicine at Mount Sinai School of Medicine in New York City and is Co-Chief of Mount Sinai's Thyroid/Endocrinology Clinic. She is a past president of the American College of Endocrinology (ACE) and of the American Association of Clinical Endocrinologists (AACE). She serves on numerous AACE committees and task forces which develop diabetes management guidelines, the diabetes inpatient management position statement and insulin resistance syndrome position statement. She was a member of the task force which developed the AMA Performance Measures for Diabetes. Dr. Cobin received her medical degree from the University of Puerto Rico School of Medicine and did residency at Beth Israel Hospital New York and endocrine fellowship at Mount Sinai in New York.

James R. Gavin III, M.D., Ph.D., is Chief Executive Officer and Chief Medical Officer of Healing Our Village, Inc., specializing in advocacy and outreach for health care professionals and minority communities. He is also Clinical Professor of Medicine and Senior Advisor of Health Affairs at Emory University. In addition, he is past president of the ADA, as well as the Morehouse School of Medicine. Dr. Gavin earned his Ph.D. degree in biochemistry from Emory University and his M.D. degree from Duke University School of Medicine.

John E. Gerich, M.D., is a Professor of Medicine at the University of Rochester School of Medicine, Program Director of the institution's General Clinical Research Center and head of its Diabetes Research Laboratory. Dr. Gerich has over 500 publications and has lectured around the world, recently on the pathogenesis of type 2 diabetes and postprandial glucose control. Dr. Gerich received his M.D. degree from Georgetown University School of Medicine.

Paul S. Jellinger, M.D., MACE, is Professor of Medicine on the voluntary faculty at the University of Miami and has served as Chief of the Section of Endocrinology at Memorial Regional Hospital in Hollywood, Florida. He is a past president of the AACE, the ACE and the Florida Endocrine Society. He has been active on the AACE Board of Directors

and has served as Chairman of the AACE Lipid Disorders Guidelines Task Force, Co-Chairman of the AACE Diabetes Roadmap Committee and contributing member of the ACE/AACE Diabetes Treatment Guidelines Committee. Dr. Jellinger received his M.D. degree from Wayne State University School of Medicine, was an NIH Fellow in endocrinology at Mt. Sinai Hospital, New York and is board certified in medicine and endocrinology. He was awarded Master of the American College of Endocrinology (MACE) in 2004.

John (Jack) L. Leahy, M.D., is Professor of Medicine and Chief of the Division of Endocrinology, Diabetes and Metabolism at the University of Vermont College of Medicine. He is also director of the Vermont Regional Diabetes Center at Fletcher Allen Health Care/University of Vermont. He has authored over 60 publications on various topics important to identifying causes of beta-cell dysfunction in diabetes as well as the clinical impact on patient therapy and patient outcomes. Dr. Leahy received his M.D. degree from the Medical College of Virginia.

Janet B. McGill, M.D., is Co-Director of the Prevention and Control Core of the Diabetes Research and Training Center at Washington University School of Medicine. She is also Associate Professor of Medicine at Washington University. She has been an active clinical researcher for over 20 years and has served on steering and safety committees for international multi-center clinical trials. Dr. McGill received her M.D. degree from Michigan State University.

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 20 million people 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.

Approximately half of people diagnosed with type 2 diabetes have not achieved adequate blood sugar level control, as measured by hemoglobin A1c (HbA1c). 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 American Diabetes Association recommends that patients with type 2 diabetes achieve a target HbA1c level of < 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 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 on-going 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 Pharmaceuticals 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 Our Ghrelin Product Candidates

Ghrelin antagonist

Elixir Pharmaceuticals believes that ghrelin, a hormone secreted by the stomach, may be a master regulator of a number of metabolic functions, including appetite and the storage and use of fat, and that the Company's ghrelin antagonist product candidates may represent a potential break-through approach for the treatment of type 2 diabetes, obesity and lipid disorders. Ghrelin plays a significant role in the regulation of glucose homeostasis, lipid profiles and

body composition. For example, genetically eliminating or “knocking out” ghrelin or the ghrelin receptor results in increased insulin sensitivity, improved triglyceride and cholesterol levels, and overall resistance to obesity in mice fed a high-fat diet.

Using structure-assisted drug design, a method of creating chemical compounds based on an understanding of the configuration of the target human receptor for the compound, Elixir has internally discovered and developed a series of potent, small molecule antagonist compounds that block the ghrelin receptor. Oral administration of the Company's compounds in animal models of diet-induced obesity and early diabetes resulted in similarly favorable metabolic effects to the knock-out models with respect to blood glucose levels, insulin resistance, HbA1c, triglycerides, total cholesterol, liver fat, body weight and white fat when compared to placebo.

Ghrelin agonist

In addition to stimulating food intake, agonists to the ghrelin receptor have been shown to increase gastric motility in animal studies. The Company believes the ghrelin agonist product candidate may have clinical utility across a broad range of indications, including diabetic gastroparesis. This compound has been the subject of extensive preclinical development and the Company has been able to capitalize on this progress with rapid completion of IND-enabling studies. Subject to successful submission to the FDA and acceptance of an IND, the Company expects to begin human clinical testing of its ghrelin agonist product candidate in 2008.

About Our Sirtuin Development Program

Building upon the Company's knowledge of the regulation of aging and metabolism, Elixir Pharmaceuticals believes to have 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 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 has an extensive intellectual property position with regards to screening, chemical composition of matter and utility claims for sirtuin modulators.

About Elixir Pharmaceuticals

Elixir Pharmaceuticals 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 interactions between specific genes and enzymes can slow the aging process, and are developing compounds that stimulate these interactions and will be used to treat a range of diseases of aging, including metabolic disease.

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