Executive Summary

AESON THERAPEUTICS INC.

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Aeson Therapeutics Inc. is a drug development company developing fluasterone as a treatment for lipid disorders and as a cancer chemoprevention agent. The company is currently conducting a Phase IIa randomized, double-blinded, placebo-controlled study examining the efficacy of fluasterone on lowering triglyceride levels in patients with metabolic syndrome.

Fluasterone will be positioned as a safe alternative to fibrates for lowering triglyceride in combination therapy with a statin in insulin-resistant patients with mixed hyperlipidemia.

Technology

Aeson has developed oral, buccal, inhalable and topical formulations of fluasterone.

Fluasterone is a synthetically stable adrenocortical steroid analogue of dehydroepiandrosterone (DHEA), a powerful anti-inflammatory molecule with unfortunate androgenic or estrogenic side effects. The U.S. Food and Drug Administration has issued an approvable letter for DHEA for maintenance of bone mineral density in patients with lupus erythematosus (GeneLabs press release, 2002).

Fluasterone has demonstrated an effect in a variety of anti-autoimmune, anti-proliferative and anti-diabetic models. Fluasterone has consistently and repeatedly shown superior efficacy to DHEA while simultaneously limiting side effects. Although the mechanism is most likely multifaceted, Aeson's evidence suggests fluasterone inhibits NF-kB activation and reduces oxidative stress.

Preclinical Models

In preclinical models of type 2 diabetes, fluasterone has shown marked anti-diabetic and triglyceride-lowering activity. Aeson has a collaborative agreement with the National Cancer Institute to develop fluasterone as a cancer-preventative agent. Preventive efficacy has been demonstrated in numerous preclinical models, including tumors of the breast, liver, colon, prostate, skin and lymphatic tissue. Fluasterone suppresses inflammation and is effective in preclinical models of chronic inflammatory disease including psoriasis, asthma, rheumatoid arthritis, multiple sclerosis and lupus erythematosus.

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Market

Fluasterone will offer a safe and effective treatment for insulin-resistant patients — such as type 2 diabetics and patients with metabolic syndrome — who have elevated triglyceride and LDL cholesterol levels. Lipid disorders represent a greater risk to these patients.

The American Diabetes Association says as many as eight million diabetics have lipid disorders. Diabetics' mortality rate from cardiovascular disease (CVD) is two to four times higher than the normal population, making CVD the leading cause of death in people with type 2 diabetes. In diabetics, elevated triglyceride levels have been associated with increased rates of CVD.

Metabolic syndrome is present in more than 20 percent of the U.S. population (Third National Health and Nutrition Examination Survey [NHANES III]). A metabolic syndrome diagnosis requires three or more of the following: high blood pressure, low HDL cholesterol, high triglyceride level, high fasting glucose concentration and abdominal obesity. A large proportion of metabolic syndrome patients have elevated triglycerides and high glucose levels.

A growing body of evidence now supports a correlation between elevated triglyceride levels and increased risk of heart disease. As a result, new treatment guidelines advocate treating patients who have triglyceride levels greater than 200 mg/dL.

Elevated triglycerides are an emerging therapy target.

Current treatments for elevated triglycerides are unable to meet the needs of all patients. Statins lower triglyceride levels 10 percent to 20 percent, which is insufficient for bringing high triglyceride levels under control. Combination therapy using fibrates and statins lowers triglyceride level 30+ percent in patients with both elevated triglyceride and LDL cholesterol levels, but also carries an increased rate of myopathy. Niacin products, a separate class of compounds for treating lipid disorders, have a tendency to elevate glucose levels, which limits their use in patients with diabetes and metabolic syndrome.

Fluasterone has demonstrated clinical efficacy in lowering triglyceride levels and preclinical efficacy in lowering glucose levels. More than 50 million Americans suffer from metabolic syndrome and as many as eight million diabetics have lipid disorders. Large proportions of both populations have elevated triglycerides levels and are insulin resistant. A fluasterone-statin combination therapy will offer a safe and effective treatment for these patients.

Intellectual Property

Aeson has numerous patents protecting fluasterone and its method of use in treating various diseases. Patent protection exists in the United States, Canada, Japan, Israel and numerous countries throughout Europe.

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