



New England Journal of Medicine Publishes Results of Two-Year BLOOM Trial Showing Lorcaserin Caused Significant Weight Loss and Improved Maintenance of Weight Loss

Lorcaserin Also Improved Values for Biomarkers That May be Predictors of Future Cardiovascular Events

SAN DIEGO and WOODCLIFF LAKE, N.J., July 14, 2010 /PRNewswire via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) and Eisai Inc. today announced that results from the two-year BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) trial will be published in the July 15, 2010, issue of the *New England Journal of Medicine*. The data presented in the article show that lorcaserin used in conjunction with behavioral modification caused significantly greater weight loss and improved maintenance of weight loss compared to placebo. Lorcaserin also improved values for biomarkers that may be predictive of future cardiovascular events, including lipid levels, insulin resistance, levels of inflammatory markers and blood pressure.

Steven R. Smith, M.D., Scientific Director of the Florida Hospital Translational Research Institute for Metabolism and Diabetes, was the lead author of the article. Neil J. Weissman, M.D., President of MedStar Health Research Institute and Professor of Medicine, Georgetown University, oversaw the echocardiographic safety evaluations that were performed in the study. Drs. Smith and Weissman served as BLOOM's co-principal investigators.

"There is a significant and growing need for effective treatment options that can help patients reduce their weight in a well-tolerated and safe manner," said Dr. Smith. "Lorcaserin patients who completed Year 1 of the BLOOM trial lost an average of 8.2% of their baseline weight and improved their cardiovascular risk factors."

"We have reached another major milestone for Arena with publication of the BLOOM results in the *New England Journal of Medicine*," said Jack Lief, Arena's President and Chief Executive Officer. "We look forward to continued execution of our plans for lorcaserin and interaction with the FDA as it conducts its review of the NDA."

At the end of Year 1 of the BLOOM trial, using Intent-to-Treat with Last Observation Carried Forward analysis (ITT-LOCF), the proportion of patients achieving at least 5% body weight loss in the lorcaserin group (47.5%) was more than twice that achieved by the placebo group (20.3%). Nearly three times as many patients achieved at least 10% weight loss in the lorcaserin group (22.6%) than in the placebo group (7.7%). Lorcaserin patients who completed the first year of the trial according to the protocol lost an average of 8.2% of their baseline weight, or approximately 18 pounds, at the end of Year 1 as compared to approximately 7 pounds in the placebo group. In Year 2, patients who continued to take lorcaserin were significantly better able to maintain their Year 1 weight loss than those who were switched to placebo.

In Year 1, lorcaserin caused significant decreases in waist circumference, BMI, glycemic parameters, high-sensitivity C-reactive protein, and fibrinogen levels compared to placebo. Total cholesterol, LDL cholesterol and triglyceride levels at Year 1 were significantly lower in the lorcaserin group than in the placebo group. Lorcaserin did not increase heart rate or blood pressure; rather, heart rate, systolic blood pressure and diastolic blood pressure decreased slightly but significantly with lorcaserin treatment compared to placebo. Quality of life, measured by the Impact of Weight on Quality of Life-Lite questionnaire, improved in both treatment groups, with a greater improvement in the lorcaserin group than in the placebo group.

At the end of Year 1, 55.4% of patients in the lorcaserin group and 45.1% of patients in the placebo group remained enrolled in the study, and 7.1% and 6.7% of patients, respectively, discontinued the study due to an adverse event. Among the most frequent adverse events reported with lorcaserin were headache (18.0% vs. 11.0%, lorcaserin vs. placebo); dizziness (8.2% vs. 3.8%); and nausea (7.5% vs. 5.4%). The rates of serious adverse events were similar in both treatment groups. The rates of depression and the incidence of anxiety and suicidal thoughts were low in both treatment groups. Lorcaserin caused no significant increase compared to placebo in the incidence of new cardiac valvulopathy.

BLOOM Trial Design

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial involving 3,182 patients in 98 sites in the United States. The trial evaluated 10 mg of lorcaserin dosed twice daily versus placebo over a two-

year treatment period in obese patients (Body Mass Index, BMI 30 to 45) with or without co-morbid conditions and overweight patients (BMI 27 to less than 30) with at least one co-morbid condition, such as hypertension, cardiovascular diseases or glucose intolerance. All patients received diet and exercise counseling, and the trial did not include any dose titration or run-in period. Patients were randomized in a 1:1 ratio to lorcaserin or placebo at baseline. At Week 52, 856 patients taking lorcaserin were re-randomized in a 2:1 ratio to continue lorcaserin or switch to placebo, and 697 patients on placebo were continued on placebo. Patients underwent echocardiography at screening, and at 6, 12, 18 and 24 months after initiating dosing in the trial; patients with FDA-defined valvulopathy were excluded from enrolling in the trial.

About Lorcaserin

Lorcaserin is a new chemical entity that is believed to act as a selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of the serotonin 2C receptor in the hypothalamus is associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the United States and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is intended for weight management and has completed a pivotal Phase 3 clinical trial program. Arena has filed an NDA for lorcaserin with the FDA, and the FDA has assigned a PDUFA date of October 22, 2010, for review of the application. Arena Pharmaceuticals GmbH, a wholly owned subsidiary of Arena Pharmaceuticals, Inc., has granted Eisai Inc. exclusive rights to market and distribute lorcaserin in the United States.

Arena Pharmaceuticals(R) and Arena(R) are registered service marks of the company.

About Eisai Inc.

Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business with fiscal year 2009 (year ended March 31, 2010) sales of approximately \$3.9 billion. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Maryland, Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit www.eisai.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the advancement, therapeutic indication and use, safety, efficacy, tolerability and potential of lorcaserin; significance of biomarkers; the need for obesity treatments; interactions with the FDA; regulatory review and potential regulatory approval and commercialization of lorcaserin; lorcaserin's patent coverage; and Arena's focus, goals, strategy, research and development programs, and ability to develop compounds, commercialize drugs and execute on its plans. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, risks related to the implementation and continuation of the marketing and supply agreement with Eisai and dependence on Eisai for commercialization of lorcaserin in the United States; regulatory authorities or advisors may not find data from Arena's clinical trials and other studies sufficient for regulatory approval; the timing and ability of Arena to receive regulatory approval for its drug candidates; the ability to enter into agreements to develop or commercialize lorcaserin and other of Arena's compounds or programs; Arena's ability to commercialize lorcaserin outside of the United States with another company or independently; the timing, success and cost of the lorcaserin program and other of Arena's research and development programs; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner Arena or others expect or at all; Arena's ability to obtain adequate funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from Eisai and Arena's collaborators. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

www.arenapharm.com

www.eisai.com

Contacts: Arena Pharmaceuticals, Inc.

Investor Inquiries:
Cindy McGee, Manager, IR and Corporate
Communications
cmcgee@arenapharm.com
858.453.7200, ext. 1479

Media Inquiries: Russo
Partners
David Schull, President
david.schull@russopartnersllc.com
858.717.2310

Contacts: Eisai Inc.

Investor Inquiries:
Dave Melin
david_melin@eisai.com
908.255.6378

Media Inquiries:
Lynn Kenney
lynn_kenney@eisai.com
201.746.2294

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