



Arena Pharmaceuticals' Lorcaserin for Obesity Passes Major Safety Milestone

- Month-12 Independent Echocardiographic Data Safety Monitoring Board Review Strengthens Lorcaserin's Emerging Cardiovascular Safety Profile -

SAN DIEGO, March 17 /PRNewswire-FirstCall/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that following a planned review by an independent Echocardiographic Data Safety Monitoring Board (EDSMB) it is continuing BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), a pivotal trial evaluating the efficacy and safety of lorcaserin hydrochloride for the treatment of obesity. The EDSMB's review of unblinded echocardiographic data performed after patients completed 12 months of dosing in the trial confirmed that differences, if any, in the rates of Food and Drug Administration (FDA)-defined valvulopathy in patients treated with lorcaserin and in the control group did not meet the EDSMB's predetermined stopping criteria. Based on the EDSMB's review of the rate of FDA-defined valvulopathy, Arena has been able to confirm that the statistical power calculations used in the design of the Phase 3 trial program to monitor patients for increased risk of developing valvulopathy are justified. The findings from the month-12 review build on the EDSMB's September 2007 review that evaluated echocardiograms after 6 months of dosing.

"This critical milestone assessing month-12 echocardiographic data strongly supports lorcaserin's cardiovascular safety profile. We believe that this exposure duration, even under a conservative interpretation of the literature, would have been sufficient to observe a fenfluramine like effect on heart valves if present. BLOOM's primary echo endpoint is based on the month-12 data," said Jack Lief, Arena's President and Chief Executive Officer. "We are committed to continued efforts to develop a robust database for submission to the FDA in our efforts to provide patients a novel, safe and effective obesity treatment."

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial involving nearly 3,200 patients in approximately 100 centers throughout the United States. The trial is evaluating a 20 mg daily dose (10 mg dosed twice daily) of lorcaserin versus placebo over a two-year treatment period in obese patients (Body Mass Index, or 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. The proportion of patients with a 5% or greater weight reduction from baseline at week 52 is the primary efficacy endpoint. Patients received echocardiograms at screening, 6 months and 12 months after initiating dosing in the trial, and will receive follow-up echocardiograms at 18 and 24 months. There are no further planned EDSMB meetings.

The BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) trial is evaluating 10 mg and 20 mg daily doses (10 mg dosed once or twice daily) of lorcaserin versus placebo over a one-year treatment period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition at about 100 sites in the United States.

The BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial is evaluating 10 mg and 20 mg daily doses (10 mg dosed once or twice daily) of lorcaserin versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 45 sites in the United States.

As in the BLOOM trial, diet and exercise are also included in the BLOSSOM and BLOOM-DM trials, and the primary efficacy endpoint is the proportion of patients with a 5% or greater weight reduction from baseline at week 52. Arena is also studying several key secondary endpoints, including changes in serum lipids and HbA1c and, in the BLOOM-DM trial, other indicators of glycemic control.

In both of these additional trials, all patients will receive echocardiograms at baseline, at month 6, and at the end of the study to assess heart valve function over time. In contrast to the BLOOM trial, however, there are no echocardiographic exclusion criteria and there is no monitoring by an independent monitoring board. The lorcaserin Phase 3 pivotal program is planned to enroll a total of approximately 7,000 patients.

"The month-12 review of the echocardiographic data significantly adds to our confidence in lorcaserin's cardiovascular safety profile," said William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer. "BLOOM is scheduled to complete about one year from now, and I'm looking forward to additional data demonstrating the potential of this novel compound to address weight loss in a highly targeted manner."

About Lorcaserin

Lorcaserin, Arena's internally discovered oral drug candidate for the treatment of obesity, is in an ongoing Phase 3 program. The compound is the first in a new class of obesity drug candidates targeting the 5-HT_{2C} serotonin receptor, which is located in the hypothalamus, a key area of the brain associated with regulation of food intake and metabolism. Results from Phase 2 studies demonstrated that treatment with lorcaserin produced highly statistically significant, progressive and dose-dependent weight loss over a 12-week period. Lorcaserin was generally well tolerated at all doses in the Phase 2 clinical trials and had no apparent effects on heart valves or pulmonary artery pressure.

About Obesity

Obesity affects tens of millions of people in the United States and poses a serious long-term threat to their health and welfare. The number of overweight and obese people has substantially increased over the past several decades. Approximately two-thirds of all adults in the United States are obese or overweight, and medical and related costs of obesity are \$123 billion per year according to a 2005 report by the International Diabetes Federation. Being obese or overweight is associated with increased risk of a number of conditions, including heart disease, stroke, diabetes, cancer and osteoarthritis. Medical treatment options for obese and overweight people currently are limited.

About Arena Pharmaceuticals

Arena is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena's most advanced drug candidate, lorcaserin, is being investigated in a Phase 3 clinical trial program for the treatment of obesity. Arena's broad pipeline of novel compounds targeting G protein-coupled receptors, an important class of validated drug targets, includes compounds being evaluated independently and with its partners, Merck & Co., Inc. and Ortho-McNeil Pharmaceutical, Inc.

Arena Pharmaceuticals® and Arena® are registered service marks of the company. "APD" is an abbreviation for Arena Pharmaceuticals Development.

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 significance of the review of echocardiographic data; the continuation of the Phase 3 program and development of lorcaserin; the sufficiency of the lorcaserin exposure duration to observe a fenfluramine like effect on heart valves; Arena's development of a lorcaserin database and the content and use of such database; Arena's efforts to provide patients a novel, safe and effective obesity treatment; the protocol, design, scope, enrollment, number, timing and other aspects of clinical trials and other studies of lorcaserin and other of Arena's drug candidates; the tolerability, side effects, safety profile, efficacy and the commercial and other potential of lorcaserin and other of Arena's drug candidates; the growth and impact of obesity; the advancement and content of Arena's pipeline; and other statements about Arena's vision, outlook, strategy, preclinical and internal and partnered clinical programs, and ability to develop compounds and commercialize drugs. 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, clinical trials and studies may not proceed at the time or in the manner Arena expects or at all, the results of clinical trials or preclinical studies may not be predictive of future results, Arena's ability to partner lorcaserin, APD125, APD791 or other of its compounds or programs, the timing, success and cost of Arena's research, out-licensing endeavors and clinical trials, Arena's ability to obtain additional financing, Arena's ability to obtain and defend its patents, the timing and receipt of payments and fees, if any, from Arena's collaborators, and Arena's ability to redeem with common stock any outstanding shares of its series B convertible preferred stock. 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.

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