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New Data From Arena Pharmaceuticals' Pivotal BLOSSOM Trial of Lorcaserin Demonstrate Improvements in Patients' Body Composition, Cardiovascular Risk Factors and Quality of Life

- Late-Breaking Data Presented at the 27th Annual Scientific Meeting of The Obesity Society Expand on Previously Announced Highly Significant Top-Line Weight Loss Results -

WASHINGTON, Oct 27, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) reported today data from the pivotal BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) Phase 3 trial that demonstrate improvements in patients' body composition, cardiovascular risk factors and quality of life. These findings add to the previously announced top-line BLOSSOM data that showed highly significant weight loss with lorcaserin over one year of treatment in 4,008 patients.

The late-breaking data were presented by Lee Kaplan, M.D., Ph.D., Associate Professor of Medicine at Harvard Medical School and Director of the Massachusetts General Hospital Weight Center, at Obesity 2009, the 27th Annual Scientific Meeting of The Obesity Society.

"Safety is of paramount importance in treating patients who are overweight or have obesity," said Dr. Kaplan. "We need new therapies that help patients reduce their weight and improve cardiovascular factors such as high blood pressure and cholesterol, while avoiding cardiac toxicity and symptoms of depression. Lorcaserin works by selectively affecting a unique and important pathway, which allows for significant weight loss and improvements in these important risk factors, along with an excellent safety and tolerability profile."

William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer, stated, "Treatment with lorcaserin offers patients the opportunity to achieve sustainable weight loss in a well-tolerated manner, resulting in improved cardiometabolic health and quality of life. In order to improve overall health, it's important to see these measurements moving in the right direction as patients reduce their weight. Based on lorcaserin's safety and efficacy profile, we expect primary care physicians to find lorcaserin an attractive first-line therapy for weight management."

Specifically, the new data demonstrate that treatment with lorcaserin over one year was associated with highly significant improvements or favorable trends compared to placebo in multiple secondary endpoints evaluated in the trial:

Body Composition

Using Intent-to-Treat Last Observation Carried Forward (ITT-LOCF) analysis, lorcaserin patients achieved highly significant improvements in Body Mass Index (BMI), waist circumference and hip circumference. Changes from baseline for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: BMI (kg/m squared), (-2.1, -1.7, -1.0); waist circumference (cm), (-6.2, -5.6, -4.2); and hip circumference (cm), (-5.3, -5.0, -3.3), ($p<0.0001$) compared to placebo for all measurements. In addition, lorcaserin patients lost significantly more body fat than the placebo patients.

Cardiovascular Risk Factors

Using ITT-LOCF analysis, lorcaserin helped improve patients' cardiovascular risk factors. Patients dosed with 10 mg of lorcaserin once or twice daily achieved statistical significance ($p<0.05$) versus placebo at Week 52 for percent change in HDL cholesterol and triglycerides and achieved favorable trends in total cholesterol and LDL cholesterol. Lorcaserin did not increase blood pressure or heart rate at any time point. Changes from baseline for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: diastolic blood pressure (mmHg), (-1.9, -1.0, -1.9); systolic blood pressure (mmHg), (-2.0, -1.1, -1.2); and heart rate (bpm), (-2.3, -1.1, -1.6).

Quality of Life

Lorcaserin did not increase depression or suicidal ideation compared to placebo. Adverse events related to depression and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows:

depression (1.9%, 1.1%, 1.8%); depressed mood (0.6%, 0.9%, 0.9%); and depressive symptoms (<0.1%, 0%, 0%).

Quality of Life, as assessed by the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire, improved to a significantly greater extent in the lorcaserin twice daily ($p<0.0001$) and lorcaserin once daily ($p<0.01$) groups as compared to placebo at Week 52. All measurements, including physical function, self esteem, sexual life, public distress and work, improved in a dose-dependent fashion.

"Our team at Arena has worked diligently to discover and develop a novel treatment for weight management that delivers the combination of efficacy, safety and tolerability. Lorcaserin patients in the pivotal program achieved meaningful weight loss and improvements in important secondary endpoints," said Jack Lief, Arena's President and Chief Executive Officer. "The Obesity Society meeting provides us with an outstanding opportunity to discuss lorcaserin's profile with the enthusiastic physicians who are in need of promising, new treatment options."

Safety and Tolerability Profile

Lorcaserin was very well tolerated. Adverse events that exceeded placebo by greater than 3% and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: headache (15.6%, 15.6%, 9.2%); nausea (9.1%, 7.6%, 5.3%); dizziness (8.7%, 6.2%, 3.9%); fatigue (8.4%, 6.6%, 4.1%); and dry mouth (5.4%, 3.4%, 2.3%). Serious adverse events occurred infrequently and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: 3.1%, 3.4% and 2.2%.

Cardiovascular Safety

The assessment of echocardiograms performed at baseline and after patients completed 6 and 12 months of dosing indicated that lorcaserin did not increase echocardiographic heart valve regurgitation. Lorcaserin met the primary safety endpoint that evaluated the rates of new FDA-defined valvulopathy in BLOSSOM at Week 52: lorcaserin 10 mg twice daily (2.0%), 10 mg once daily (1.4%) and placebo (2.0%). The integrated BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM echocardiography data set rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA.

New data demonstrate that similar numbers of mitral insufficiency and aortic insufficiency shifts were reported for patients on lorcaserin and placebo. In patients with pre-existing FDA-defined valvulopathy at baseline, changes in valvular regurgitant scores did not differ between the placebo and lorcaserin groups. The majority of patients experienced either no change or an improvement in valvular regurgitation.

Previously Announced Efficacy Data

The previously announced BLOSSOM data demonstrated that lorcaserin was highly efficacious, achieving statistical significance on all three co-primary efficacy endpoints, and was very well tolerated. Lorcaserin patients achieved highly significant categorical and absolute weight loss over 52 weeks of treatment. About two-thirds (63.2%) of lorcaserin patients dosed twice daily who completed the trial according to the protocol lost at least 5% of their weight, compared to 34.9% of patients on placebo, and more than one-third (35.1%) of these lorcaserin patients lost at least 10% of their weight, compared to 16.1% for placebo. The average weight loss for lorcaserin patients dosed twice daily was 17.0 pounds, compared to 8.7 pounds for placebo. The top quartile of lorcaserin patients who completed the trial according to protocol and had their Week 52 weight recorded lost an average of 35.1 pounds.

Patient Disposition

BLOSSOM evaluated 4,008 patients with an average BMI of 35.9 and baseline weight of 220 pounds. The Week 52 completion rate was higher for patients on lorcaserin 10 mg twice daily (57.2%) and 10 mg once daily (59.0%) compared to patients on placebo (52.0%). Discontinuations for adverse events were low and as follows: lorcaserin 10 mg twice daily (7.2%), 10 mg once daily (6.2%) and placebo (4.6%).

BLOSSOM Trial Design

BLOSSOM is a double-blind, randomized, placebo-controlled trial in approximately 100 sites in the US. The trial evaluated 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients (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 trial did not include dose titration or a run-in period. Patients were randomized at baseline in a 2:2:1 ratio to lorcaserin 10 mg twice daily, placebo or lorcaserin 10 mg once daily. Patients received echocardiograms at baseline, month 6 and at the end of the trial to assess heart valve function over time. In contrast to the BLOOM trial, there were no echocardiographic exclusion criteria for entry into BLOSSOM and there was no oversight or interim data review monitoring

by an independent safety monitoring board.

Phase 3 Program Overview

The lorcaserin Phase 3 program consists of three trials: BLOOM, BLOSSOM and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus). Enrollment in the lorcaserin Phase 3 program is complete with approximately 7,800 patients. Positive results from BLOOM were presented at the 69th Scientific Sessions of the American Diabetes Association in June 2009. BLOOM and BLOSSOM comprise the Phase 3 pivotal registration program and will be the basis for the lorcaserin NDA submission. BLOOM-DM, which is planned as a supplement to the NDA, is evaluating 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes at about 60 sites in the US.

A standardized program of moderate diet and exercise guidance is included in the Phase 3 program. The program's hierarchically ordered co-primary efficacy endpoints are: the proportion of patients achieving 5% or greater weight loss after 12 months, the difference in mean weight loss compared to placebo after 12 months, and the proportion of patients achieving 10% or greater weight loss after 12 months. Arena is also studying several key secondary endpoints, including changes in serum lipids, markers of inflammation and insulin resistance, and in the BLOOM-DM trial, other indicators of glycemic control.

About Lorcaserin

Lorcaserin is a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of this receptor is strongly associated with feeding behavior and satiety. Arena has patents that cover lorcaserin in the US 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 Weight Management

The National Institutes of Health reported in 2007 that about 65% of US adults are overweight or obese. A 2009 publication in *Health Affairs* estimated the annual medical burden of obesity in the US to be $147 billion in 2008. Studies have shown that weight loss of 5% to 10% is medically significant and results in meaningful improvements in cardiovascular risk factors and a significant reduction in the incidence of type 2 diabetes in patients with glucose intolerance.

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 weight management. Arena has a broad pipeline of novel compounds targeting G protein-coupled receptors, an important class of validated drug targets, which includes compounds being evaluated independently and with partners, including Merck & Co., Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc.

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 development, advancement, therapeutic indication and use, tolerability, safety, selectivity, efficacy, and regulatory approval of lorcaserin; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; lorcaserin's commercial and other potential, including in managing weight, meeting patients' and physicians' needs, changing treatment, improving health and quality of life and generating interest; significance of the lorcaserin trial results and the completion of the lorcaserin Phase 3 pivotal registration program; the FDA's approval process and requirements; the risk of developing valvulopathy; the potential of the lorcaserin Phase 3 program and its results to satisfy the FDA's approval requirements; future activities, results and announcements relating to lorcaserin, including submitting an NDA for lorcaserin, submitting the BLOOM-DM results as a supplement to the NDA, and commercializing lorcaserin; the impact of weight loss on health; lorcaserin's patent coverage; and Arena's strategy, internal and partnered 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, the timing, success and cost of Arena's lorcaserin program and other of its research and development programs; results of clinical trials or preclinical studies may not be predictive of future results; clinical trials and

studies may not proceed at the time or in the manner Arena expects or at all; Arena's ability to partner or commercialize lorcaserin or other of its compounds or programs; the timing and ability of Arena to receive regulatory approval for its drug candidates; Arena's ability to obtain additional funds; Arena's ability to obtain and defend its patents; and the timing and receipt of payments and fees, if any, from 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.

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