



Arena Pharmaceuticals Reports Positive, Highly Significant BLOSSOM Trial Results for Weight Management; NDA Submission on Track for December

- **Lorcaserin Meets all Primary Endpoints and FDA Benchmark -**
- **63% of Lorcaserin Patients Who Complied with the Protocol Lost at Least 5% of Their Weight -**
- **Lorcaserin Patients in the Top Quartile Achieved Average Weight Loss of 16% or 35 Pounds -**
- **Combined Phase 3 BLOOM and BLOSSOM Data Set Confirms Lorcaserin's Excellent Safety and Tolerability Profile and Rules Out Heart Valve Effect -**
- **Conference Call and Webcast Presentation Scheduled for 8:00 a.m. ET on September 18, 2009 -**

SAN DIEGO, Sept 18, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) reported today positive, highly significant top-line results from the BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) trial. BLOSSOM confirms the results previously reported for the BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) trial and completes the lorcaserin Phase 3 pivotal registration program of 7,190 patients evaluated for up to two years. Arena plans to submit a New Drug Application, or NDA, for lorcaserin to the US Food and Drug Administration, or FDA, in December.

In the one-year BLOSSOM trial, lorcaserin met all primary efficacy and safety endpoints. Patients achieved highly significant categorical and absolute weight loss. Lorcaserin was very well tolerated and was not associated with depression or suicidal ideation. The integrated echocardiographic data set from BLOSSOM and BLOOM rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA. Treatment with lorcaserin also resulted in significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk.

"Today there are extremely limited options to meet the needs of physicians and patients in the real world clinical practice of weight management," said Steven R. Smith, M.D., Executive Director of the Florida Hospital Clinical Research Institute. "Physicians need options that have the potential to help the typical obese patient lose significant weight by staying on a safe and well-tolerated treatment. The clinical data show lorcaserin is a solution that could provide physicians with a weight-loss medication applicable for broad use in the majority of their patients who need to lose weight and improve their health. BLOSSOM demonstrated that nearly two-thirds of lorcaserin patients lost a medically meaningful amount of body weight while avoiding unwanted side effects and a complicated titration program."

"History has taught us that the marriage of efficacy and safety is of critical importance in treating patients. Neither is sufficient without the other. With its excellent safety and tolerability profile, we expect lorcaserin to change the way primary care doctors treat the broad cross-section of overweight and obese patients with pharmacotherapy," said Jack Lief, Arena's President and Chief Executive Officer. "With the completion of our robust Phase 3 pivotal program, we will focus on the NDA filing, work with the FDA during the review process and prepare for the commercialization of lorcaserin."

Arena plans to present detailed data from both the BLOOM and BLOSSOM trials at the 27th Annual Scientific Meeting of The Obesity Society, scheduled for October 24-28 in Washington, D.C.

Efficacy

Per Protocol Results

Lorcaserin was highly effective in helping patients achieve significant weight loss using multiple measurements. Patients treated with 10 mg of lorcaserin dosed twice daily (BID) who completed the 52-week trial according to protocol demonstrated the benefit of long-term treatment with lorcaserin:

- 63.2% of patients lost at least 5% of their body weight ($p < 0.0001$);
- 35.1% of patients lost at least 10% of their body weight ($p < 0.0001$);
- Patients lost an average of 17.0 pounds, or 7.9% of their body weight;
and

- The quartile of lorcaserin patients with the greatest weight loss (among those with a Week 52 weight recorded) lost an average of 35.1 pounds, or 16.3% of their body weight.

Of the placebo patients who completed the trial, 34.9% and 16.1% achieved at least 5% and 10% weight loss, respectively, and the average weight loss was 8.7 pounds, or 3.9%. The top quartile of lorcaserin patients lost 36% more body weight than the top quartile of placebo patients.

For the patients treated with 10 mg of lorcaserin dosed once daily (QD) and completing the 52-week trial according to protocol, 53.1% lost at least 5% of their body weight and 26.3% lost at least 10% of their body weight. The average weight loss in the lorcaserin 10 mg once daily group was 14.3 pounds, or 6.5%. As with the higher dose, all results were highly statistically significant ($p < 0.0001$ compared to placebo).

Intent-to-Treat Last Observation Carried Forward (ITT-LOCF) Results

Measurements of efficacy using ITT-LOCF analysis also showed that lorcaserin met all primary endpoints. This analysis includes all patients who were randomized and returned for at least one weight measurement. Patients treated with 10 mg of lorcaserin once or twice daily achieved highly statistically significant categorical and average weight loss after 12 months:

Lorcaserin 10 mg Twice Daily

- 47.2% of patients treated with 10 mg of lorcaserin dosed twice daily lost at least 5% of their body weight compared to 25.0% for placebo ($p < 0.0001$). This result satisfies the efficacy benchmark in the most recent FDA draft guidance which provides that a weight-management product can be considered effective if the proportion of patients who lose at least 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant;
- 22.6% of patients treated with 10 mg of lorcaserin dosed twice daily lost at least 10% of their body weight compared to 9.7% for placebo ($p < 0.0001$);

Lorcaserin 10 mg Once Daily

- 40.2% of patients treated with 10 mg of lorcaserin dosed once daily lost at least 5% of their body weight ($p < 0.0001$); and
- 17.4% of patients treated with 10 mg of lorcaserin dosed once daily lost at least 10% of their body weight ($p < 0.0001$).

Patients who took lorcaserin 10 mg twice daily achieved an average weight loss of 5.9% of their body weight, compared to 2.8% for placebo ($p < 0.0001$). Similarly, patients who took lorcaserin 10 mg once daily achieved an average weight loss of 4.8% of their body weight ($p < 0.0001$).

BLOSSOM Confirms BLOOM

In BLOSSOM, as in BLOOM, lorcaserin's excellent tolerability allowed patients to begin treatment at the full dose immediately, without a titration period, and achieve rapid weight loss. As in BLOOM, significant weight loss compared to placebo was shown at the first trial visit, two weeks following randomization.

The efficacy for the BLOOM and BLOSSOM trials after one year of treatment are summarized in the table below.

BLOOM

BLOSSOM

	10 mg BID*	Placebo	10 mg BID*	10 mg QD*	Placebo
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>/=5% weight loss (Per protocol)	66.4%	32.1%	63.2%	53.1%	34.9%
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>/=5% weight loss (ITT-LOCF)	47.5%	20.3%	47.2%	40.2%	25.0%
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>/=10% weight loss (Per protocol)	36.2%	13.6%	35.1%	26.3%	16.1%
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>/=10% weight loss (ITT-LOCF)	22.6%	7.7%	22.6%	17.4%	9.7%
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Mean weight loss (Per protocol)	8.2%	3.4%	7.9%	6.5%	3.9%
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Mean weight loss (ITT-LOCF)	5.8%	2.2%	5.9%	4.8%	2.8%
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* p<0.0001 compared to placebo

"Lorcaserin demonstrated consistent results in the BLOOM and BLOSSOM trials, which together evaluated nearly 7,200 patients for up to two years," said William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer. "These results support lorcaserin's potential to meet the need for a safe, effective and well-tolerated weight loss medication. There are only two drugs that are approved by the FDA for long-term treatment, and new mechanistic and better tolerated approaches could greatly improve the treatment of patients who are obese or significantly overweight."

Safety and Tolerability Profile

Lorcaserin was very well tolerated. No adverse event rate in the lorcaserin group exceeded the placebo group by more than 4%. The most frequent adverse events and their rates for patients who took lorcaserin twice daily, lorcaserin once daily or placebo, respectively, were as follows: upper respiratory infection (12.7%, 14.5%, 12.6%); nasopharyngitis (12.5%, 11.7%, 11.8%) and headache (10.0%, 10.5%, 7.6%).

Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported at a similar rate in each treatment group. Serious adverse events, or SAEs, occurred infrequently: one death occurred in the placebo group, no SAEs of seizure were reported and the number of neuropsychiatric SAEs in lorcaserin patients did not exceed the number in the placebo group.

Cardiovascular Safety

The integrated BLOOM and BLOSSOM echocardiography data set rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA. Echocardiographic evaluations showed no association between lorcaserin and the development of heart valve insufficiency. Rates of new FDA-defined valvulopathy in BLOSSOM at Week 52 were as follows: lorcaserin 10 mg twice daily (2.0%), 10 mg once daily (1.4%) and placebo (2.0%).

"The echocardiographic safety data show no risk of valvulopathy," commented Neil J. Weissman, M.D., Director, Cardiac Ultrasound and Ultrasound Core Labs, President, MedStar Research Institute, and Professor of Medicine, Georgetown University. "In the individual and combined BLOOM and BLOSSOM data sets there is no evidence of a difference in the development of valve disease in lorcaserin patients versus control for up to two years of continuous use. No prospective echocardiographic program has ever studied this many patients for this period of time."

Secondary Endpoints

Treatment with lorcaserin over one year was associated with significant improvements or strongly favorable trends compared to placebo in multiple secondary endpoints, including blood pressure and lipids.

Patient Disposition

BLOSSOM evaluated 4,008 patients with an average body mass index, or 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%).

Conference Call & Webcast

Arena will host a conference call and webcast presentation to discuss the results at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time) on September 18, 2009. Jack Lief, President and Chief Executive Officer; Dominic P. Behan, Ph.D., Senior Vice President and Chief Scientific Officer; William R. Shanahan, M.D., Vice President and Chief Medical Officer; and Christen M. Anderson, M.D., Ph.D., Vice President, Clinical Development, will host the conference call and webcast.

The conference call may be accessed by dialing 888.312.3047 for domestic callers and 719.325.2234 for international callers. Please specify to the operator that you would like to join the "Lorcaserin BLOSSOM Trial Results" conference call. The conference call and slide presentation will be webcast live under the investor relations section of Arena's website at www.arenapharm.com, and will be archived there for 30 days following the call. Please connect to Arena's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

BLOSSOM Trial Design

BLOSSOM is a double-blind, randomized, placebo-controlled trial that enrolled 4,008 patients 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 the FDA Draft Guidance

The FDA draft guidance document "Developing Products for Weight Management" dated February 2007 provides recommendations regarding the development of drugs for the indication of weight management. It contains two alternate efficacy benchmarks. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of subjects who lose greater than or equal to 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant.

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.

Arena Pharmaceuticals(R) and Arena(R) 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 BLOSSOM and BLOOM results and the completion of the lorcaserin Phase 3 pivotal registration program; the development, advancement, therapeutic indication, tolerability, safety, selectivity and efficacy of lorcaserin; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; the engineering of weight management drug candidates; the FDA's guidance, process and requirements; the potential of the lorcaserin Phase 3 program and its results to satisfy the FDA's approval requirements, including with regard to efficacy and safety; the risk of developing valvulopathy; future activities, results and announcements relating to lorcaserin, including submitting an NDA for lorcaserin, working with the FDA during the review process, submitting the BLOOM-DM results as a supplement to the NDA, and commercializing lorcaserin; lorcaserin's commercial and other potential, including in managing weight, changing treatment, improving health and generating interest; the impact of weight loss on health; the treatment of patients with new mechanistic and better tolerated approaches; lorcaserin's patent coverage; and Arena's focus, 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 and top-line results are preliminary; 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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