



## **Positive Data from Arena Pharmaceuticals' Pivotal BLOOM Trial Demonstrate that Lorcaserin Significantly Improved Markers of Cardiovascular Risk and Glycemic Parameters and was not Associated with Depression or Suicidal Ideation**

**- Data Presented at the 27th Annual Scientific Meeting of The Obesity Society Expand on Previously Announced Highly Significant Results -**

**- Lorcaserin Patients Lost About One-Third of Their Excess Weight -**

WASHINGTON, Oct 25, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) reported that data from the pivotal BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) Phase 3 trial demonstrate lorcaserin significantly increased excess weight loss, improved markers of cardiovascular risk and glycemic parameters, and was not associated with depression or suicidal ideation. Additional subgroup analyses showed that lorcaserin caused the greatest improvements in lipid profiles, glycemic parameters and other markers of cardiovascular risk in patients in the highest risk categories. The new data were presented at Obesity 2009, the 27th Annual Scientific Meeting of The Obesity Society.

"There is an enormous unmet need for new weight management treatments to help address the obesity epidemic. If approved, lorcaserin's unique combination of efficacy, safety and tolerability will make it suitable as first-line therapy for weight management," said Steven R. Smith, M.D., Executive Director of the Florida Hospital Translational Research Institute for Metabolism and Diabetes. "Based on the results from lorcaserin's pivotal program, physicians and patients can expect treatment with lorcaserin, along with a lifestyle modification program, to result in average weight loss of nearly 20 pounds and a significant reduction in their excess weight over one year, while improving important risk factors and quality of life. Lorcaserin was very well tolerated; the most common side effect was mild and transient headache early in treatment."

Specifically, the new data show that lorcaserin increased excess weight loss during Year 1 of the BLOOM trial. Lorcaserin patients who completed the trial according to protocol lost 31.0% of their excess weight compared to 12.0% for the placebo group. This measurement is based on a normal Body Mass Index, or BMI, of 25. In addition to the previously announced improvements in glycemic parameters, including fasting glucose, fasting insulin and HOMA-IR, lorcaserin patients also achieved highly significant improvements in HbA1C over one year of treatment ( $p < 0.0001$ ). The greatest improvements were observed in patients with abnormal baseline values.

Quality of Life, as assessed by the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire, also improved to a significantly greater extent in the lorcaserin group than the placebo group at Week 52 ( $p < 0.005$ ). Lorcaserin patients achieved improvements over placebo in all subscores of the IWQOL-Lite, including physical function, self esteem, sexual life, public distress and work.

In addition to the previously announced tolerability data, today's presentation also reported that lorcaserin demonstrated no increase in depression or suicidal ideation compared to placebo. Depression and suicidal ideation were monitored prospectively using the Beck Depression Inventory-II (BDI-II) and by adverse event reporting. At Week 52, 18.0% of lorcaserin patients and 16.1% of placebo patients reported at least a five-point improvement from baseline in BDI-II. A smaller number of lorcaserin patients had increases in the BDI-II total score as compared to placebo. Adverse events related to depression and their total rates at Year 1 for patients who took lorcaserin or placebo, respectively, were 3.1% and 3.0%. In addition, cumulative incidence of suicidal ideation was prospectively evaluated by administration of the BDI-II Questionnaire and did not differ between the lorcaserin and placebo groups at each measurement through two years of treatment.

Christen M. Anderson, M.D., Ph.D., Arena's Vice President of Clinical Development stated, "Drug candidates that act on the central nervous system are currently under tremendous scrutiny for any association with depression or suicidal ideation. Lorcaserin's selective activation of an important receptor associated with reduced food intake avoids these liabilities. We believe the data presented at Obesity 2009 will support our new drug application and we look forward to working with the FDA to provide physicians and patients with lorcaserin."

Previously announced BLOOM data demonstrate that lorcaserin helped patients achieve clinically meaningful weight loss and maintenance of weight loss over two years of treatment. In the per protocol population, nearly two-thirds (66.4%) of lorcaserin

patients lost at least 5% of their weight, compared to 32.1% of patients on placebo, and over one-third (36.2%) of lorcaserin patients lost at least 10% of their weight, compared to 13.6% for placebo. The average weight loss in this population was 17.9 pounds in the lorcaserin group, compared to 7.4 pounds in the placebo group. Using ITT-LOCF analysis, 67.9% of Year 1 lorcaserin responders maintained at least 5% weight loss during Year 2, compared to 50.3% for those patients re-randomized from lorcaserin treatment in Year 1 to placebo in Year 2.

Lorcaserin improved patients' lipid profiles, insulin resistance and markers of inflammation, with the greatest improvements observed in those with abnormal values at the start of the study. Treatment with lorcaserin was well tolerated, resulting in very few adverse events with greater frequency than the placebo group, and did not increase cardiac valvulopathy. Lorcaserin's tolerability profile eliminates the need for titration; patients began treatment on the full dose and achieved rapid weight loss. Almost one-third of lorcaserin patients lost at least 5% of their body weight by Week 8.

#### *Patient Disposition*

BLOOM evaluated 3,182 patients with an average BMI of 36.2 and baseline weight of 220 pounds. The Week 52 completion rate was higher for patients on lorcaserin (55.4%) compared to patients on placebo (45.1%). Discontinuation rates for adverse events were similar in the lorcaserin and placebo groups for Year 1 and Year 2 (7.1% vs. 6.7% and 3.0% vs. 3.0%, respectively).

#### *BLOOM Trial Design*

BLOOM, the first of three lorcaserin Phase 3 trials, is a double-blind, randomized, placebo-controlled trial in approximately 100 sites in the US. The trial evaluated 10 mg of lorcaserin dosed twice daily versus placebo over a two-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 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 to switch to placebo, and 697 patients on placebo were continued on placebo. Patients received echocardiograms 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.

#### *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.

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### *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 elimination of the need for titration; the protocol, design, scope, enrollment and other aspects of the lorcaserin trials; lorcaserin's commercial and other potential, including in managing weight, changing treatment, improving health and quality of life and generating interest; physician and patient expectations relating to lorcaserin; significance of the lorcaserin results and the completion of the lorcaserin Phase 3 pivotal registration program; the FDA's approval process and requirements; 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, working with the FDA during the review process, 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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