



## **Arena Pharmaceuticals Announces Workforce Reduction and Provides Lorcaserin Regulatory Update**

SAN DIEGO, Jan. 27, 2011 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today a reduction of its US workforce of approximately 25%, or 66 employees. As a result of the workforce reduction, which Arena plans to complete around March 28, 2011, the company expects to incur restructuring charges, primarily in the first quarter of 2011, of approximately \$3.8 million in connection with one-time employee termination costs. Arena expects the reduction to decrease annualized cash expenditures by approximately \$13.5 million. Arena will focus its resources on working to obtain regulatory approval of lorcaserin, seeking collaborators for the commercialization of lorcaserin outside of the US and advancing select earlier-stage research and development programs independently or in partnership.

"We deeply regret having to reduce our workforce, greatly appreciate the efforts of the employees affected by today's announcement and thank them for their significant contributions to Arena," said Jack Lief, Arena's President and Chief Executive Officer. "This workforce reduction strengthens our financial position by focusing our resources on the prioritized programs that we believe have the greatest potential to deliver value."

Following the reduction in workforce, Arena will remain a fully integrated R&D organization. The company has aligned its resources with its corporate priorities, which include lorcaserin and select research and development programs. Arena plans to complete this year the ongoing Phase 1a clinical trial for APD811, an agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension, and advance APD334, an agonist of the S1P1 receptor intended for the treatment of multiple sclerosis, toward clinical development. Arena also plans to explore exclusive partnering opportunities for its broad array of internally discovered, oral GPR119 agonists, including APD597 and next-generation compounds, and non-exclusive partnering opportunities for its portfolio of patents and patent applications related to the discovery and development of GPR119 receptor agonists.

Arena plans to provide additional details on the financial impact of the reduction in workforce and other cost savings with the issuance of 2011 financial guidance during its 2010 year-end results conference call.

### **Lorcaserin Regulatory Update**

In December 2010, Arena reported on its discussions with the US Food and Drug Administration (FDA) at the end-of-review meeting for the lorcaserin New Drug Application (NDA), including Arena and Eisai's plans to address the lorcaserin Complete Response Letter (CRL) and the expectation to resubmit the NDA to the FDA by the end of 2011. Arena is continuing its discussions with the FDA to finalize protocols for activities that are designed to address the issues raised by the FDA or that otherwise are related to the assessment of the benefit-risk profile of lorcaserin. The FDA has requested that Arena submit protocols prior to initiating certain studies and expects to provide Arena with its comments and recommendations within approximately one month of each protocol submission.

As previously announced, the majority of activities relate to the three non-clinical issues outlined in the CRL. The first issue relates to the diagnostic uncertainty in the classification of mammary masses in female rats. As part of addressing this issue, Arena has convened five independent pathologists to re-adjudicate the female rat mammary tumor diagnoses from the rat carcinogenicity study. The FDA has reviewed and agreed to Arena's protocol, and this work is ongoing.

The second issue relates to demonstrating a mechanism for mammary adenocarcinoma in female rats that is reasonably irrelevant to human risk. Arena is planning experiments to further test the theory that lorcaserin causes mammary tumors in rats by increasing prolactin. The FDA has recommended a dosing duration of no less than three months to establish a causal relationship between lorcaserin, prolactin elevation and mammary tumor development in rats. Subsequent to the end-of-review meeting, the FDA requested that Arena consider performing a separate 12-month study in female rats that would test whether transient prolactin elevation mediated by short-term exposure to lorcaserin can result in mammary tumors in rats.

The third issue relates to the unidentified mode of action and unclear safety margin for lorcaserin-emergent brain astrocytoma in male rats. Because the mechanism for induction of astrocytomas in rats is unknown, Arena will focus on providing additional information designed to demonstrate that an adequate safety margin exists for humans. Arena plans to conduct non-clinical experiments, including receptor pharmacology studies, and a small clinical study to measure lorcaserin concentrations in

human cerebrospinal fluid to provide additional data that may be informative for predicting human brain levels at therapeutic doses of lorcaserin. At the FDA's recommendation subsequent to the end-of-review meeting, Arena will expand the receptor studies to more fully characterize lorcaserin's activity at the 5-HT<sub>2B</sub> receptor to further assess the risk of valvulopathy.

In addition, the FDA has expressed concern over the abuse potential of lorcaserin and the available data related to abuse potential, and has recommended that Arena modify and repeat two non-clinical studies to provide additional safety information for labeling and scheduling decisions. Arena is preparing to initiate these studies pending a meeting that is scheduled to take place with the Controlled Substances Staff in February.

"Our ongoing discussions with the FDA reflect our commitment to addressing the issues raised in the CRL to the agency's satisfaction," Lief said. "We now have a greater understanding of the FDA's position as we move forward with our plans to resubmit the lorcaserin NDA."

Arena is working to address the FDA's concerns and continues to believe that it can resubmit the lorcaserin NDA by the end of 2011. Arena is in continuing discussions with the FDA, and it is possible that certain activities may be required that could impact the timeline for resubmission or potential FDA approval of lorcaserin.

### **About Lorcaserin**

Lorcaserin is intended for weight management, including weight loss and maintenance of weight loss, in patients who are obese (BMI greater than or equal to 30) or patients who are overweight (BMI greater than or equal to 27) and have at least one weight-related co-morbid condition. 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 believed to be involved in the control of appetite and metabolism. Arena has patents that cover lorcaserin in the United States and other jurisdictions that in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

Arena submitted an NDA for lorcaserin to the FDA in December 2009, and the FDA issued a Complete Response Letter (CRL) in October 2010. In the CRL, the FDA outlined non-clinical and clinical reasons for its decision and provided recommendations relating to addressing such issues.

### **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. Arena's wholly owned subsidiary, Arena Pharmaceuticals GmbH, has granted Eisai Inc. exclusive rights to market and distribute lorcaserin in the United States following FDA approval of the NDA for lorcaserin.

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

### **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 reduction of Arena's workforce, including the expected size, timing, related charges and benefits, and other expected impact of such reduction; Arena remaining a fully integrated R&D organization; future research, development, regulatory and partnering focus, plans and activities; partnering opportunities and the advancement and potential of Arena's programs; discussions with the FDA and the results of such discussions; submission of protocols to the FDA and the FDA's response; ongoing and future studies and activities to address the CRL and the FDA's concerns and requests; the potential resubmission of the lorcaserin NDA and the related timing; the advancement, therapeutic indication and use, safety, efficacy, tolerability, and mechanism of action of lorcaserin; lorcaserin's patent coverage; the Eisai collaboration and potential activities thereunder; and Arena's focus, goals, strategy, research and development 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 following: the risk that negative effects related to the reduction of Arena's workforce may be greater than anticipated; the risk that Arena may not realize the benefits expected from such reduction; the risk that regulatory authorities may not find data and other information related to Arena's clinical trials and other studies meet safety or efficacy requirements or are otherwise sufficient for regulatory approval; the timing of regulatory review and approval is uncertain; Arena's response to the CRL for the lorcaserin NDA may not be submitted when anticipated or the information provided in such response may not satisfy the FDA; the FDA may request other information prior to or after Arena resubmits the lorcaserin NDA or approval of the lorcaserin NDA; unexpected or unfavorable new data; risks related to commercializing new products; Arena's ability to obtain and defend its patents; the timing, success and cost 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; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from collaborators; and satisfactory resolution of pending and any future litigation or other disagreements with others. 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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