



## **Arena Pharmaceuticals Announces European Medicines Agency's Acceptance of Lorcaserin Marketing Authorization Application for Weight Control**

### **-- Company Also Receives FDA Confirmation of May 10th Lorcaserin Advisory Committee Meeting --**

SAN DIEGO, March 26, 2012 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (NASDAQ: ARNA) announced today that the European Medicines Agency (EMA) has accepted the filing of a Marketing Authorization Application (MAA) for lorcaserin, an investigational drug candidate intended for weight control, including weight loss and maintenance of weight loss, in patients who are obese (BMI  $\geq 30$ ) or patients who are overweight (BMI  $\geq 27$ ) and have at least one weight-related co-morbid condition. The acceptance of the MAA filing begins the EMA's review process.

In addition, Arena reported that the US Food and Drug Administration (FDA) has confirmed the scheduling of an Endocrinologic and Metabolic Drugs Advisory Committee meeting to discuss the lorcaserin New Drug Application (NDA) resubmission on May 10, 2012.

"Substantial evidence shows that being overweight or obese can have dire human health consequences coupled with tremendous economic burden," said Jack Lief, Arena's President and Chief Executive Officer. "With applications under review for approval in both the United States and European Union, lorcaserin has the potential to provide a new treatment for physicians to help patients lose weight and improve their overall cardiometabolic health."

Arena's preparations for the upcoming advisory committee meeting are being led by Craig M. Audet, Arena's Vice President of Global Regulatory Affairs, Dominic P. Behan, Ph.D., Arena's Chief Scientific Officer, and William R. Shanahan, Jr., M.D., Arena's Chief Medical Officer. Following the lorcaserin NDA resubmission and MAA filing, Christen M. Anderson, M.D., Ph.D., will be retiring from Arena at the end of the month.

"We are working diligently with Eisai Inc. to prepare for the FDA advisory committee meeting in May," said Mr. Audet. "We look forward to lorcaserin's PDUFA date in June as well as reporting on developments related to the MAA throughout the year."

### **About Lorcaserin**

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, Europe 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 resubmitted the lorcaserin NDA to the FDA in December 2011, and the agency has assigned a new PDUFA target date of June 27, 2012. Eisai Inc. has exclusive rights to market and distribute lorcaserin in the United States subject to FDA approval of the lorcaserin NDA. An MAA for lorcaserin was accepted for filing by the EMA in March 2012. Arena currently owns rights to lorcaserin outside of the United States.

### **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.

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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 advancement, therapeutic indication and use, safety, efficacy, mechanism of action and potential of lorcaserin; the regulatory review of the lorcaserin NDA resubmission and MAA, including

the timing for the FDA to complete its review; the FDA advisory committee meeting, the discussion on the NDA resubmission and related preparations; developments related to the MAA; the Eisai collaboration and activities thereunder; the potential approval, commercialization and impact of lorcaserin; lorcaserin's patent coverage; 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 timing of regulatory review is uncertain and Arena's applications for regulatory approval of lorcaserin may not be reviewed when or as anticipated; the FDA may not complete its review of the lorcaserin NDA resubmission by the PDUFA date; the occurrence, timing and results of FDA advisory committee meetings relating to lorcaserin and other drug candidates; nonclinical and clinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Arena or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; data and other information related to lorcaserin and Arena's other research and development programs may not meet safety, efficacy or other regulatory requirements or otherwise be sufficient for regulatory review or approval; 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 expected or at all; having 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 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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