October 23, 2010

FDA Issues Complete Response Letter for Lorcaserin New Drug Application

SAN DIEGO and WOODCLIFF LAKE, N.J., Oct. 23, 2010 /PRNewswire via COMTEX News Network/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) and Eisai Inc. announced that the US Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding Arena's New Drug Application (NDA) for lorcaserin. Lorcaserin is intended for weight management, including weight loss and maintenance of weight loss, in patients who are obese (Body Mass Index, or BMI, >/= 30) or patients who are overweight (BMI >/= 27) and have at least one weight-related co-morbid condition.

The FDA has completed its review of the NDA and determined that it cannot approve the application in its present form. In the CRL, the FDA outlined the non-clinical and clinical reasons for their decision.

The non-clinical issues identified by the FDA included diagnostic uncertainty in the classification of mammary masses in female rats, unresolved exposure-response relationship for lorcaserin-emergent mammary adenocarcinoma, and unidentified mode of action and unclear safety margin for lorcaserin-emergent brain astrocytoma.

The CRL included the following requests related to the non-clinical issues: provide a detailed accounting of all slides prepared from female rats that contributed to mammary tumor incidence data in each update to the FDA and to the final study report; in consultation with the FDA, identify an independent pathologist or group of pathologists to re-adjudicate all mammary and lung tissues (neoplastic and nonneoplastic lesions) from all female rats; demonstrate that the apparent increase in aggressiveness of adenocarcinoma in rats administered lorcaserin is reasonably irrelevant to human risk assessment; and provide additional data/information regarding the distribution of lorcaserin to the CNS in animals and human subjects that would clarify or provide a better estimate of astrocytoma exposure margins.

With respect to the clinical reasons, the FDA stated in the CRL that the weight loss efficacy of lorcaserin in overweight and obese individuals without type 2 diabetes is marginal and recommended that Arena submit the final study report of the BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial. The FDA also stated in the letter that in the event evidence cannot be provided to alleviate concern regarding clinical relevance of the tumor findings in rats, additional clinical studies may be required to obtain a more robust assessment of lorcaserin's benefit-risk profile.

The BLOOM-DM trial evaluated lorcaserin versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes mellitus. The trial is complete, and Arena expects to announce top-line results in the next few weeks and to have a completed study report by the end of the year.

Additionally, the FDA stated in the CRL that it would recommend placement of lorcaserin in Schedule IV of the Controlled Substance Act based on its review of the materials submitted in the NDA. The CRL provided the opportunity to complete preclinical studies that may lead to a different recommendation.

"This is an important step for us toward the FDA's approval of lorcaserin," said Jack Lief, Arena's President and Chief Executive Officer. "While the complete response letter provides us with recommendations from the agency, we intend to meet with the FDA to obtain further clarity on the approval path and timeline. We will work with the agency to address the issues with our NDA as quickly as possible."

Arena intends to request a Type A meeting with the FDA to clarify its requests, and, if the meeting is granted, the FDA's guidance states that it should occur within 30 days of the request.

Lonnel Coats, President and Chief Executive Officer of Eisai Inc., stated, "Eisai is committed to collaborating with Arena to address the FDA's requests. Obesity is an epidemic in America, and our goal is to bring lorcaserin to physicians and patients who need additional weight loss options."

Conference Call & Webcast

Arena will host a conference call and webcast on Monday, October 25, 2010, at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time). The conference call may be accessed by dialing 877.643.7155 for domestic callers and 914.495.8552 for

international callers. Please specify to the operator that you would like to join the "Lorcaserin" conference call. The conference call 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.

Lorcaserin New Drug Application

The lorcaserin NDA is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years.

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 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.

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 and has completed a pivotal Phase 3 clinical trial program. 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.

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

About Eisai Inc.

Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business with fiscal year 2009 (year ended March 31, 2010) sales of approximately $3.9 billion. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Maryland, Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit www.eisai.com.

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 future activities related to the complete response letter, including meeting with the FDA, the outcome of such meeting and working with the FDA to address issues related to the NDA; Arena's response to the complete response letter; the importance of the complete response letter; Arena's collaboration with Eisai and activities thereunder; BLOOM-DM, including the announcement of top-line results and the completion of the related study report; the advancement, therapeutic indication and use, safety, efficacy, tolerability, mechanism of action, scheduling and regulatory review and approval 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 risk that regulatory authorities may not find data from Arena's clinical trials and other studies sufficient for regulatory approval; the timing of regulatory review and approval is uncertain; Arena's response to the complete response letter may not be submitted in a timely manner and/or the information provided in such response may not satisfy the FDA; the FDA may request additional information prior to approval; unexpected new data; Arena's ability to obtain and defend its patents; risks related to commercializing new products; 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; the timing and receipt of payments and fees, if any, from Eisai and Arena's 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.

Contacts: Arena Pharmaceuticals, Inc.

Investor Inquiries:	Media Inquiries: Russo Partners
Cindy McGee	David Schull
cmcgee@arenapharm.com	david.schull@russopartnersllc.com
858.453.7200, ext. 1479	858.717.2310

www.arenapharm.com

Contacts: Eisai Inc.

Investor Inquiries:	Media Inquiries:
Dave Melin	Lynn Kenney
david_melin@eisai.com	lynn_kenney@eisai.com
908.255.6378	201.746.2294

www.eisai.com

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