August 9, 2011

Arena and Eisai Announce Results of Re-Adjudication of Rat Mammary Tumors from Lorcaserin Carcinogenicity Study

- Report to be Included in Response to Lorcaserin CRL -

SAN DIEGO and WOODCLIFF LAKE, N.J., Aug. 9, 2011 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (NASDAQ: ARNA) and Eisai Inc. announced today results from a Pathology Working Group's (PWG) re-adjudication of female rat mammary tumor diagnoses from a two-year rat carcinogenicity study of lorcaserin. Arena convened the PWG in response to the lorcaserin Complete Response Letter (CRL), which questioned the certainty of the female rat mammary tumor classifications. The PWG reviewed relevant tissues and reported that mammary fibroadenomas (benign tumors) were distinguishable from mammary adenocarcinomas (malignant tumors). The PWG reported shifts in the numbers of both tumor types from the initial report included in the lorcaserin New Drug Application (NDA) and that adenocarcinomas were no longer numerically higher than the control group in the lorcaserin low- and mid-dose groups.

"We believe the PWG's report should further clarify the female rat mammary tumor diagnoses which, in combination with other data, may be helpful in assessing human risk," said William R. Shanahan, M.D., Arena's Senior Vice President and Chief Medical Officer.

The PWG's re-adjudication is one of the activities intended to address the observation of mammary tumors in female rats and is part of the overall plan to submit a response to the lorcaserin CRL. Additional activities intended to address the CRL are ongoing.

Findings from Initial and PWG Reports

The PWG consisted of five pathologists contracted by Arena. Arena consulted the US Food and Drug Administration (FDA) in selecting these pathologists. According to the PWG's re-adjudication, the incidence of adenocarcinomas was numerically lower than the control group in both the lorcaserin low (10 mg/kg/day) and mid (30 mg/kg/day) dose groups and was statistically higher than the control group in the lorcaserin high (100/kg/day) dose group, and the incidence of fibroadenomas was statistically higher than the control group for all three lorcaserin dose groups. The incidences of adenocarcinomas and fibroadenomas from the initial report and the PWG report are summarized below.

Percent of Female Rats with Mammary Adenocarcinoma or Fibroadenoma				
Dose	Control	10 mg/kg/day	30 mg/kg/day	100 mg/kg/day
N	65	65	65	75
Mammary Adenocarcinoma (Malignant)				
Initial Report	43.1%	52.3%	53.9%	80.0%
PWG Report	40.0%	32.3%	36.9%	68.0%
Mammary Fibroadenoma (Benign)				
Initial Report	30.8%	72.3%	81.5%	60.0%
PWG Report	36.9%	83.1%	84.6%	68.0%

In addition, the PWG reported that the incidence of mammary adenomas (benign tumors) was 1.5%, 3.1%, 7.7%, 5.3%, the incidence of mammary carcinosarcomas (malignant tumors) was 0%, 0%, 0%, 1.3%, the incidence of lung metastases of mammary gland origin was 0%, 1.5%, 7.7%, 6.7%, and the incidence of lung metastases of non-mammary gland origin was 0%, 4.6%, 6.2%, 2.7% for the control and lorcaserin low-, mid- and high-dose groups, respectively. No mammary adenomas were diagnosed in the initial report, the incidence of mammary carcinosarcomas did not change from the initial report, and the incidence of lung metastases of both mammary and non-mammary origin were reported together in the initial report as 0%, 6.2%, 13.8% and 8.0% for the control and lorcaserin low-, mid- and high-dose groups, respectively.

It is important to note that the FDA may have a different interpretation of the re-adjudication and subsequent conclusions of the PWG. There may be other factors in addition to incidence that may contribute to the FDA's assessment of human risk

for the finding of mammary tumors in female rats. The information reported in this press release summarizes a report containing voluminous and detailed data that will be reviewed by the FDA. The FDA may analyze or weigh the importance of data from the report differently than the PWG or Arena.

About Lorcaserin

Lorcaserin is an investigational drug candidate intended for weight management, 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. 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 a NDA for lorcaserin to the FDA in December 2009, and the FDA issued a CRL in October 2010. Arena's wholly owned subsidiary, Arena Pharmaceuticals GmbH, has granted Eisai Inc. exclusive rights to market and distribute lorcaserin in the United States subject to FDA approval of the NDA for lorcaserin.

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 Pharmaceuticals® and Arena® are registered service marks of the company.

About Eisai Inc.

Eisai Inc. was established in 1995 and is ranked among the top-25 US 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. Eisai's areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the US pharmaceutical operation of Eisai Co., Ltd., a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world.

Eisai has a global product creation organization that includes US-based R&D facilities in 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/us.

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, tolerability, mechanism of action and potential of lorcaserin; the significance of the PWG's re-adjudication and report, including in assessing human risk and clarifying, and addressing, the female rat mammary tumor diagnoses; the FDA's assessment of human risk, analysis and weighting of data and interpretation of the PWG's re-adjudication, report and findings; the response to the CRL for the lorcaserin NDA, including related plans and activities; the Eisai collaboration and potential activities thereunder; 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 FDA may not accept the PWG's re-adjudication, report or findings, may interpret and analyze the data differently and may reach different conclusions; the timing of regulatory review and approval is uncertain; the risk that data and other information related to Arena's research and development programs may not meet safety or efficacy requirements or otherwise be sufficient for regulatory approval; Arena's response to the CRL for the lorcaserin NDA or submission of a Marketing Authorization Application for regulatory approval of lorcaserin may not be submitted when anticipated, if at all; the FDA may request other information prior to or after Arena submits such response 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 expected 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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