



December 22, 2010

## **Arena and Eisai Complete End-of-Review Meeting with FDA for Lorcaserin New Drug Application**

**-- Meeting Provides Additional Clarity on Next Steps Toward Approval --**  
**-- Arena to Host Conference Call and Webcast at 8:30 a.m. Eastern Time Today --**

SAN DIEGO and WOODCLIFF LAKE, N.J., Dec. 22, 2010 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) and Eisai Inc. announced today the completion of an end-of-review meeting with the US Food and Drug Administration (FDA) for the lorcaserin New Drug Application (NDA).

"The meeting discussions reinforce our position that we have a path forward to seek FDA approval of lorcaserin," said Jack Lief, Arena's President and Chief Executive Officer. "Based on guidance we have received from the agency, we are executing several activities and expect to resubmit the lorcaserin NDA by the end of 2011. As we continue discussions with the FDA to refine elements of our plan, we may identify ways to shorten this timeline. We will provide more details about our plan on the conference call and webcast this morning."

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. The end-of-review meeting with the FDA included a discussion of the FDA's position on issues identified in the CRL and Arena's plan to respond.

### **Conference Call & Webcast**

Arena will host a conference call and webcast today, December 22, 2010, at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) to discuss its plan to address the CRL and resubmit the lorcaserin NDA. 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](http://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.

### **About Lorcaserin**

Lorcaserin is 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.

### **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 New Drug Application for lorcaserin.

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 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 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 US pharmaceutical operation of Eisai Co., Ltd.

Eisai has a global product creation organization that includes US-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](http://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 discussions with the FDA and the results of such discussions; next steps and the path forward to seek FDA approval of lorcaserin; the potential resubmission of the lorcaserin NDA and the related timing; the potential FDA approval and commercialization of lorcaserin; the advancement, therapeutic indication and use, safety, efficacy, tolerability, and mechanism of action of lorcaserin; 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 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 complete response letter for the lorcaserin NDA may not be submitted in a timely manner 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.

Contacts: Arena Pharmaceuticals, Inc.

Investor Inquiries:	Media Inquiries: Russo Partners
Cindy McGee	David Schull
<a href="mailto:cmcgee@arenapharm.com">cmcgee@arenapharm.com</a>	<a href="mailto:david.schull@russopartnersllc.com">david.schull@russopartnersllc.com</a>
858.453.7200, ext. 1479	858.717.2310

Contacts: Eisai Inc.

Investor Inquiries:	Media Inquiries:
Dave Melin	Lynn Kenney
<a href="mailto:david_melin@eisai.com">david_melin@eisai.com</a>	<a href="mailto:lynn_kenney@eisai.com">lynn_kenney@eisai.com</a>
908.255.6378	201.746.2294

[www.arenapharm.com](http://www.arenapharm.com)      [www.eisai.com](http://www.eisai.com)

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