BELVIQ® (lorcaserin HCl) CIV Data Featured in Five Abstracts to be Presented at ObesityWeek(SM) 2013

WOODCLIFF LAKE, N.J. and SAN DIEGO, Nov. 13, 2013 /PRNewswire/ -- Eisai Inc. and Arena Pharmaceuticals, Inc., (NASDAQ:ARNA) announced today that five abstracts highlighting new data analyses from the BELVIQ® (lorcaserin HCl) Phase 3 clinical trial program will be presented during ObesityWeekSM 2013, hosted by The Obesity Society and the American Society for Metabolic and Bariatric Surgery. ObesityWeekSM 2013 is taking place November 11-16 in Atlanta, Georgia.

The following abstracts highlighting BELVIQ data will be presented:

- **Impact of Lorcaserin on Glycemic Control in Overweight and Obese Patients with Type 2 Diabetes: Analysis of Week 52 Responders and Non-responders**  
  Oral Presentation: T-32-OR
  
  This post-hoc analysis of a previously published Phase 3 trial, BLOOM-DM, evaluated the effects of lorcaserin on glycemic parameters in overweight and obese patients (body mass index, or BMI, 27-45 kg/m²) with type 2 diabetes who achieved greater than or equal to 5% weight loss at week 52. 509 patients in the BLOOM-DM trial were randomized to lorcaserin 10 mg twice daily or placebo with diet and exercise counseling. This analysis assessed fasting plasma glucose, HbA1c, and use of anti-hyperglycemic medications at week 52, stratified by week 52 weight response.

- **Effects of Lorcaserin on Lean and Fat Mass Loss in Patients with Type 2 Diabetes Mellitus from the BLOOM-DM Study of Obese and Overweight Patients**  
  Poster Presentation: T-738-P
  
  This analysis of patients from the BLOOM-DM trial evaluated the loss of lean and fat body mass and overall weight loss achieved over one year as determined by dual-emission X-ray absorptiometry (DXA) in a subset of 63 patients with type 2 diabetes. Together with diet and exercise counseling, patients were randomized to lorcaserin or placebo, and DXA scans were performed at baseline, six months, and one year. Lean mass and body fat were stratified by baseline HbA1c.

- **Effects of Lorcaserin on Lean and Fat Mass Loss in the BLOSSOM Study of Obese and Overweight Patients**  
  Poster Presentation: T-739-P
  
  This analysis of patients from the BLOSSOM trial evaluated the loss of lean and fat body mass relative to overall weight loss achieved over one year as determined by DXA in a subset of 189 obese and overweight patients. Together with diet and exercise counseling, patients were randomized to lorcaserin or placebo, and DXA scans were performed at baseline, six months, and one year. Lean mass and body fat were analyzed by magnitude of weight loss.

- **Number Needed to Treat Analysis of Lorcaserin in Overweight and Obese Patients**  
  Poster Presentation: T-742-P
  
  A Number Needed to Treat (NNT) analysis was conducted for three Phase 3 trials of lorcaserin: BLOOM, BLOSSOM and BLOOM-DM. This NNT analysis evaluated one-year endpoints including weight loss, reduction in waist circumference, and change in HbA1C (BLOOM-DM only) in week 12 responders - defined as patients achieving greater than or equal to 5% weight loss after 12 weeks of treatment - and the overall lorcaserin population, in comparison to the placebo group.

- **Health-related Quality of Life in Overweight and Obese Patients Treated with Lorcaserin**  
  Poster Presentation: T-753-P
  
  This analysis assessed the impact of lorcaserin on health-related quality of life in overweight and obese patients enrolled in the Phase 3 BLOOM and BLOSSOM trials.
About BELVIQ® (lorcaserin HCl) CIV

BELVIQ is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain. The exact mechanism of action of BELVIQ is not known. For more information about BELVIQ, click here for the full US FDA-approved Product Information or visit www.BELVIQ.com.

BELVIQ is approved by the US Food and Drug Administration. Eisai markets and distributes BELVIQ in the United States, and Arena manufactures and supplies the finished commercial product from its facility in Switzerland. Eisai and Arena’s BELVIQ marketing and supply agreement covers most territories worldwide.

Indications

BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:

- 30 kg/m² or greater (obese), or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes).

Limitations of Use:

- The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss, including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations, have not been established.
- The effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

IMPORTANT SAFETY INFORMATION

Contraindication

- BELVIQ should not be taken during pregnancy or by women who are planning to become pregnant.

Warnings and Precautions

- BELVIQ is a serotonergic drug. The development of potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported during use of serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors, and selective serotonin reuptake inhibitors, tricyclic antidepressants, bupropion, triptans, dietary supplements such as St. John’s Wort and tryptophan, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors), dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists, particularly when used in combination. Patients should be monitored for the emergence of serotonin syndrome symptoms or NMS-like reactions, including agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, nausea, vomiting, diarrhea, and muscle rigidity. Treatment with BELVIQ and any concomitant serotonergic or antidopaminergic agents should be discontinued immediately if the above events occur, and supportive symptomatic treatment should be initiated.
- Patients should not take BELVIQ in combination with drugs that have been associated with valvular heart disease (e.g., cabergoline). In clinical trials, 2.4% of patients taking BELVIQ and 2.0% of patients taking placebo developed valvular regurgitation: none of these patients was symptomatic. BELVIQ should be used with caution in patients with congestive heart failure (CHF). Patients who develop signs and symptoms of valvular heart disease, including dyspnea, dependent edema, CHF, or a new cardiac murmur, should be evaluated and discontinuation of BELVIQ should be considered.
- Impairment in attention, memory, somnolence, confusion, and fatigue, have been reported in patients taking BELVIQ. Patients should not drive a car or operate heavy machinery until they know how BELVIQ affects them.
- The recommended dose of 10 mg twice daily should not be exceeded, as higher doses may cause euphoria, hallucination, and dissociation. Monitor patients for the development or worsening of depression, suicidal thoughts or behaviors, and/or any changes in mood. Discontinue BELVIQ in patients who develop suicidal thoughts or behaviors.
- Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus who are being treated with antidiabetic medications, so measurement of blood sugar levels before and during treatment with BELVIQ is recommended. Decreases in doses of antidiabetic medications or changes in medication regimen should be considered.
- Men who experience priapism should immediately discontinue BELVIQ and seek emergency medical attention. BELVIQ should be used with caution with erectile dysfunction medications. BELVIQ should be used with caution in men who have conditions that might predispose them to priapism (e.g., sickle cell anemia, multiple myeloma, or...
leukemia), or in men with anatomical deformation of the penis (e.g., angulation, cavernosal fibrosis, or Peyronie's disease).

- Because BELVIQ may cause a slow heartbeat, it should be used with caution in patients with a history of bradycardia or heart block greater than first degree.
- Consider monitoring for CBC changes, prolactin excess, and pulmonary hypertension.

**Most Common Adverse Reactions**

- In patients without diabetes: headache (17%), dizziness (9%), fatigue (7%), nausea (8%), dry mouth (5%), and constipation (6%).
- In patients with diabetes: hypoglycemia (29%), headache (15%), back pain (12%), cough (8%), and fatigue (7%).

**Nursing Mothers**

- BELVIQ should not be taken by women who are nursing.

BELVIQ is a federally controlled substance (CIV) because it may be abused or lead to dependence.

**About Eisai Inc.**

At Eisai Inc., human health care is our goal. We give our first thoughts to patients and their families, and helping to increase the benefits health care provides. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., our passionate commitment to patient care is the driving force behind our efforts to help address unmet medical needs. We are a fully integrated pharmaceutical business with discovery, clinical, manufacturing and marketing capabilities. Our key areas of commercial focus include oncology and specialty care (Alzheimer's disease, epilepsy and metabolic disorders). To learn more about Eisai Inc., please visit us at [www.eisai.com/US](http://www.eisai.com/US).

Eisai Inc. has affiliates that are part of a global product creation organization that includes R&D facilities in Massachusetts, New Jersey, North Carolina and Pennsylvania, as well as a global demand chain organization that includes manufacturing facilities in Maryland and North Carolina. Eisai's global areas of R&D focus include neuroscience; oncology; metabolic disorders; vascular, inflammatory and immunological reaction; and antibody-based programs.

**About Arena Pharmaceuticals**

Arena is a biopharmaceutical company focused on discovering, developing and commercializing novel drugs that target G protein-coupled receptors, or GPCRs, to address unmet medical needs. BELVIQ® (lorcaserin HCl), Arena's internally discovered drug, is approved in the United States, and is under review for regulatory approval in additional territories. Arena's US operations are located in San Diego, California, and its operations outside of the United States, including its commercial manufacturing facility, are located in Zofingen, Switzerland. For more information, visit Arena's website at [www.arenapharm.com](http://www.arenapharm.com).

Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, Inc. BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH.

**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, regulatory review and approval, and potential of BELVIQ or lorcaserin; and Arena's focus, plans, goals, strategy, expectations, research and development programs, and ability to discover and 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: risks related to commercializing drugs, including regulatory, manufacturing and supply issues and the availability and use of BELVIQ; cash and revenues generated from BELVIQ, including the impact of competition; Arena's revenues will be based in part on estimates, judgment and accounting policies, and incorrect estimates or disagreement regarding estimates or accounting policies may result in changes to Arena's guidance or previously reported results; the timing and outcome of regulatory review is uncertain, and BELVIQ may not be approved for marketing when expected or ever in combination with another drug, for another indication or using a different formulation or in any other territory for any indication; regulatory decisions in one territory may impact other regulatory decisions and Arena's business prospects; government and commercial reimbursement and pricing decisions; risks related to relying on collaborative arrangements; the timing and receipt of payments and fees, if any, from collaborators; the entry into or modification or termination of collaborative arrangements;
unexpected or unfavorable new data; 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 any of Arena's research and development may not meet regulatory requirements or otherwise be sufficient for further research and development, regulatory review or approval or continued marketing; Arena's ability to obtain and defend patents; the timing, success and cost of Arena's research and development; 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; 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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