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Eisai and Arena Pharmaceuticals Announce Presentation of BELVIQ® (lorcaserin HCl) Data at 2016 Annual Obesity Week Meeting

WOODCLIFF LAKE, N.J. and SAN DIEGO, Nov. 3, 2016 /PRNewswire/ -- Eisai Inc. and Arena Pharmaceuticals, Inc. (NASDAQ: ARNA) announced today the presentation of one oral presentation and one poster at Obesity Week(SM) regarding new data on BELVIQ® (lorcaserin HCl) CIV. Hosted by The Obesity Society and the American Society for Metabolic and Bariatric Surgery, the meeting is taking place from October 31-November 4, 2016, in New Orleans, Louisiana at the Morial Convention Center.

Presentations of note include:

Effects of Lorcaserin on Lipid Parameters in Patients With Overweight or Obesity and Dyslipidemia

- Oral Presentation Number: T-OR-2070
- Session: Energy Balance: Causes and Consequences
- Presentation: 11/3/16; 3:45 pm - 5:15 pm
- Location: Ernest N. Morial Convention Center; Room 206-207

A post-hoc analysis that evaluated triglycerides (TG) and non-high-density lipoprotein cholesterol (non-HDL-C) after treatment with lorcaserin in a subset of patients without T2DM and with dyslipidemia at baseline (defined as: Fasting TG ≥200 mg/dL and/or non-HDL-C ≥160 mg/dL)

Health-Related Quality of Life in Randomized Controlled Trials of lorcaserin for Obesity Management: What Mediates Improvement?

- Poster Number: T-P3478
- Session: Pharmacological and Surgical Treatment of Obesity and Others
- Presentation: 11/4/16; 12:00 pm - 1:30 pm
- Location: Ernest N. Morial Convention Center; Exhibit Hall

A pooled analysis from three lorcaserin Phase 3 trials (BLOOM, BLOSSOM and BLOOM DM) to determine whether lorcaserin is associated with greater improvements in health-related quality of life and whether these improvements are solely attributable to weight loss.

This release discusses an investigational use for an FDA-approved product. It is not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical

development or gain FDA approval.

INDICATION FOR BELVIQ® (lorcaserin HCl) CIV

BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults 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 (eg, 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 (eg, 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 (eg, cabergoline). In clinical trials, 2.4% of patients taking BELVIQ and 2.0% of patients taking placebo developed valvular regurgitation: none of these patients were 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 (eg, sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (eg, 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 (> 5% and more common than placebo)

- 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.

For more information about BELVIQ, see full Prescribing Information.

About Eisai Inc.

At Eisai Inc., *human health care (hhc)* 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., we have a passionate commitment to patient care that is the driving force behind our efforts to discover and develop innovative therapies to help address unmet medical needs.

Eisai is a fully integrated pharmaceutical business that operates in two global business groups: oncology and neurology (dementia-related diseases and neurodegenerative diseases). Each group functions as an end-to-end global business with discovery, development, and marketing capabilities. Our U.S. headquarters, commercial and clinical development organizations are located in New Jersey; our discovery labs are in Massachusetts and Pennsylvania; and our global demand chain organization resides in Maryland and North Carolina. To learn more about Eisai Inc., please visit us at www.eisai.com/US.

About Arena Pharmaceuticals

We are a biopharmaceutical company focused on developing novel, small molecule drugs across a range of therapeutic areas. We have three primary proprietary investigational clinical programs: etrasimod (APD334) in Phase 2 evaluation for ulcerative colitis, APD371 entering Phase 2 evaluation for the treatment of pain associated with Crohn's disease, and ralinepag (APD811) in Phase 2 evaluation for pulmonary arterial hypertension (PAH). Additionally, we have collaborations with the following pharmaceutical companies: Eisai Co., Ltd. and Eisai Inc. (commercial stage), Axovant Sciences Ltd. (Phase 2 candidate), and Boehringer Ingelheim International GmbH (preclinical candidate).

Our US operations are located in San Diego, California. Our primary clinical operations are located in Zug, Switzerland, and our commercial manufacturing for BELVIQ is located in Zofingen, Switzerland.

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 therapeutic potential of BELVIQ; the need to address obesity; Eisai's commitment; and Arena's focus, plans, goals, strategy, expectations, 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: risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and the availability and use of BELVIQ; cash and revenues generated from BELVIQ; Arena may need additional funds to advance all of its programs, and you may not agree with the manner Arena allocates its resources; the risk that Arena's revenues are 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 receive any additional marketing approvals; 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 (or Arena or a collaborator may not pursue) further research and development, regulatory review or approval or continued marketing; Arena's and third parties' intellectual property rights; the timing, success and cost of Arena's research and development and related strategy and decisions; 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; 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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