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Arena Pharmaceuticals and Eisai Announce FDA Approval of BELVIQ® (lorcaserin HCl) for Chronic Weight Management in Adults who are Overweight with a Comorbidity or Obese

-- First Prescription Weight-Loss Treatment Approved by FDA in 13 Years --

-- Eisai to Launch BELVIQ in U.S. Following DEA's Completion of Scheduling Review --

SAN DIEGO and WOODCLIFF LAKE, N.J., June 27, 2012 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (NASDAQ: ARNA) and Eisai Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved BELVIQ (pronounced BEL-VEEK) 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). The indication includes the following limitations of use: The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss and the effect of BELVIQ on cardiovascular morbidity and mortality have not been established.

"The FDA approval of BELVIQ is an important development for patients who struggle with obesity or are overweight with comorbidities and need help with chronic weight management beyond diet and exercise," said Jack Lief, Arena's President and Chief Executive Officer. "We thank our entire team and the patients who participated in our clinical trial program for making this achievement possible."

Three double-blind, randomized, placebo-controlled trials demonstrated that BELVIQ along with diet and exercise was more effective than diet and exercise alone at helping patients lose 5% or more of their body weight after one year and managing the weight loss for up to two years.

"Diet, exercise and behavioral therapy alone may not result in sustained weight loss for many overweight and obese people trying to lose weight," said Lonnel Coats, President and Chief Executive Officer, Eisai Inc. "BELVIQ represents an important therapeutic option for physicians responsible for the medical management of their patients who are overweight or obese."

In clinical trials, the most common adverse reactions for patients without diabetes treated with BELVIQ were headache, dizziness, fatigue, nausea, dry mouth, and constipation. In patients with diabetes, the most common adverse reactions were hypoglycemia, headache, back pain, cough, and fatigue.

The FDA has recommended that BELVIQ be classified by the U.S. Drug Enforcement Administration (DEA) as a scheduled drug. The DEA will review the FDA's recommendation and determine the final scheduling designation. Once the DEA has provided the final scheduling designation, Eisai will announce when BELVIQ will be available to patients and physicians in the United States.

Arena will manufacture and supply the finished commercial product from its facility in Switzerland, and Eisai will market and distribute BELVIQ in the United States.

As part of the approval of BELVIQ, the companies committed to conduct post-marketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. The cardiovascular outcomes trial will include echocardiographic assessments.

Conference Call & Webcast

Arena will host a conference call and webcast today, June 27, 2012, at 2 p.m. Eastern Time (11 a.m. Pacific Time) to provide a business update. 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 "BELVIQ" 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.

About BELVIQ (lorcaserin HCl)

BELVIQ (lorcaserin hydrochloride) is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain.

For more information about BELVIQ, [click here](http://us.eisai.com/package_inserts/BelviqPI.pdf) for the full prescribing information or go to http://us.eisai.com/package_inserts/BelviqPI.pdf

BELVIQ Phase 3 Clinical Trial Program

The BELVIQ Phase 3 clinical trial program consisted of three double-blind, randomized, placebo-controlled trials: BLOOM (**B**ehavioral modification and **L**orcaserin for **O**verweight and **O**besity **M**anagement), BLOSSOM (**B**ehavioral modification and **L**orcaserin **S**econd **S**tudy for **O**besity **M**anagement) and BLOOM-DM (**B**ehavioral modification and **L**orcaserin for **O**verweight and **O**besity **M**anagement in **D**iabetes **M**ellitus). All three trials included a standardized program of diet, moderate exercise and behavioral counseling for both the placebo and BELVIQ groups.

BLOOM evaluated BELVIQ versus placebo over a two-year treatment period in 3,182 non-diabetic, obese (BMI of 30 to 45 kg/m²) adult patients (18 to 65 years old) with or without comorbid conditions and non-diabetic, overweight (BMI of 27 to 29.9 kg/m²) adult patients with at least one weight related comorbid condition.

BLOSSOM evaluated BELVIQ versus placebo over a one-year treatment period in 4,008 non-diabetic, obese (BMI of 30 to 45 kg/m²) adult patients (18 to 65 years old) with or without comorbid conditions and non-diabetic, overweight (BMI of 27 to 29.9 kg/m²) adult patients with at least one weight related comorbid condition.

BLOOM-DM evaluated BELVIQ versus placebo over a one-year treatment period in 604 obese (BMI of 30 to 45 kg/m²) and overweight (BMI of 27 to 29.9 kg/m²) adult patients (18 to 65 years old) with type 2 diabetes who were receiving oral antihyperglycemic agents.

Indications

BELVIQ is indicated to be used along with 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

- **Pregnancy:** BELVIQ should not be taken during pregnancy or by women who are planning to become pregnant.
- **Nursing:** BELVIQ should not be taken while breastfeeding.
- **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions:** BELVIQ and certain medicines for depression, migraine, the common cold, and mood, anxiety, psychotic or thought disorders or other medical problems may affect each other causing serious or life-threatening side effects. Patients should tell their doctor if they are taking medicines to treat any of these conditions such as: triptans, tricyclics, lithium, selective serotonin uptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), or antipsychotics; linezolid, an antibiotic; tramadol; dextromethorphan, an over-the-counter medicine used to treat the common cold or cough; over-the-counter supplements such as tryptophan or St. John's Wort. BELVIQ and these medicines should be discontinued immediately and symptomatic treatment measures should be initiated if patients taking BELVIQ and these other medicines experience any of the following: mental changes such as agitation, hallucinations, confusion, or other changes in mental status; coordination problems, uncontrolled muscle spasms, or muscle twitching (overactive reflexes); restlessness; racing or fast heartbeat, high or low blood pressure; sweating or fever; nausea, vomiting, or diarrhea; or muscle rigidity (stiff muscles).
- **Valvular Heart Disease:** Certain weight loss drugs have been associated with problems with the valves in the heart. Patients taking BELVIQ who have trouble breathing, swelling of the arms, legs, ankles, or feet, dizziness, fatigue, or weakness that will not go away, or fast or irregular heartbeat should call their doctor right away. Before taking BELVIQ,

patients should tell their doctor if they have or had heart problems including congestive heart failure, or heart valve problems. Patients should not take BELVIQ in combination with drugs that have been associated with valvular heart disease (such as cabergoline). Patients who develop signs and symptoms of valvular heart disease while taking BELVIQ should be evaluated and discontinuation of BELVIQ should be considered by their doctor.

- **Changes in Attention or Memory:** Problems with thinking, sleepiness, confusion, and fatigue have been reported in patients taking BELVIQ.
- Patients taking BELVIQ should not drive a car or operate heavy machinery until they know how BELVIQ affects them.
- **Mental Problems:** Taking BELVIQ at higher than the recommended dose may cause psychiatric problems such as: hallucinations, feeling high or in a very good mood (euphoria), feelings of standing next to yourself or out of your body (disassociation). The recommended dose of 10 mg twice daily should not be exceeded. Patients should be monitored for the development or worsening of depression, suicidal thoughts or behaviors, and/or any changes in mood. BELVIQ should be discontinued if patients develop suicidal thoughts or behaviors.
- **Low Blood Sugar (Hypoglycemia):** Weight loss can cause low blood sugar in people with type 2 diabetes mellitus who are on medicines to treat it such as metformin, insulin, or sulfonylureas. Blood sugar levels should be monitored for patients who take BELVIQ. Changes to medicines may be needed if low blood sugar develops.
- **Painful Erections (Priapism):** If patients taking BELVIQ experience an erection lasting more than 4 hours, whether it is painful or not, they should stop using BELVIQ and call their doctor or go to the nearest emergency room right away. BELVIQ should be taken with caution by men who have conditions that might predispose them to priapism (e.g., sickle cell anemia, multiple myeloma, or leukemia), or in men with a deformed penis. Patients should tell their doctor if they take medicines used to treat erectile dysfunction.
- **Slow Heartbeat:** BELVIQ may cause a slow heartbeat. Patients taking BELVIQ should tell their doctor if they have a history of a slow heartbeat or heart block.
- **Decreases in Blood Cell Count:** BELVIQ may cause decreases in red or white blood cell count. A doctor may do tests to check a patient's blood cell count during treatment with BELVIQ.
- **Increase in Prolactin:** BELVIQ may increase the amount of a hormone the body makes, called prolactin. Patients taking BELVIQ should tell their doctor if their breasts begin to make milk or have a milky discharge or if their breasts begin to increase in size.
- **Increased Pressure in the Arteries of the Lung (Pulmonary Hypertension):** Certain weight loss drugs have been associated with the rare but life-threatening side effect of increased pressure in the arteries of the lung. It is unknown if BELVIQ increases the risk for this condition.
- **Most Common Adverse Reactions In Non-Diabetic Patients:** Headache, dizziness, fatigue, nausea, dry mouth, and constipation.
- **Most Common Adverse Reactions in Diabetic Patients:** Hypoglycemia, headache, back pain, cough, and fatigue.
- Response to BELVIQ should be evaluated at 12 weeks of treatment to determine if therapy should be discontinued.

For more information about BELVIQ, [click here](#) for the full prescribing information or go to http://us.eisai.com/package_inserts/BelviqPI.pdf

About Arena Pharmaceuticals

Arena Pharmaceuticals, Inc., is a 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. For more information about Arena Pharmaceuticals, please visit www.arenapharm.com.

Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, Inc.

BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH.

About Eisai Inc.

Eisai Inc. was established in 1995 and began marketing its first product in the United States in 1997. Since that time, Eisai Inc. has rapidly grown to become a fully integrated pharmaceutical business. The company serves as the U.S. 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 U.S.-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 importance of the FDA approval of BELVIQ; the safety, efficacy, mechanism of action, DEA scheduling and commercialization of BELVIQ; the use of BELVIQ by patients and physicians; rights and obligations under the marketing and supply agreement with Eisai; future studies of BELVIQ; 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 timing and outcome of DEA, EMA and other regulatory review is uncertain; limitations on the indicated uses, restricted distribution methods and other limitations on BELVIQ or, if approved, any of our other drug candidates; risks related to commercializing drugs, including regulatory, manufacturing and supply issues and the pace of market acceptance; cash and revenues generated from BELVIQ, including timing and impact of competition; government and commercial reimbursement and pricing decisions; risks related to relying on collaborative agreements; the timing and receipt of payments and fees, if any, from collaborators; 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 we 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 our research and development programs may not meet safety, efficacy or other regulatory requirements or otherwise be sufficient for regulatory review, approval or continued marketing; our ability to obtain and defend our patents; the timing, success and cost of our 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; 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.

Contacts: Arena Pharmaceuticals, Inc. Contacts: Eisai Inc.
858.453.7200

Investor Inquiries: Russo Partners Investor Inquiries:
Cindy McGee Alex Scott
cindy.mcgee@russopartnersllc.com alex_scott@eisai.com
619.213.6995 201.746.2177

Media Inquiries: Russo Partners Media Inquiries:
David Schull Marcia Diljak
david.schull@russopartnersllc.com marcia_diljak@eisai.com
858.717.2310 201.746.2236

www.arenapharm.com

www.eisai.com/us

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