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Eisai Inc. and Arena Pharmaceuticals Announce Availability of Once-Daily BELVIQ XR® (lorcaserin HCl) Extended-Release Tablets

New FDA-Approved Formulation Offers Patients a Once-Daily Dosing Option for Chronic Weight Management

WOODCLIFF LAKE, N.J. and SAN DIEGO, Oct. 3, 2016 /PRNewswire/ -- Eisai Inc. and Arena Pharmaceuticals, Inc. (NASDAQ: ARNA) today announced the availability of BELVIQ XR® (lorcaserin HCl) CIV extended-release 20 mg tablets, a new once-daily dosing option that may help some patients achieve and maintain weight loss.



"With more than 78 million adults who are obese in this country and obesity rates on the rise, there is an increased need for additional therapeutic options to help patients better manage their weight," said Caroline Apovian, M.D., Professor of Medicine at Boston University School of Medicine. "A once-daily, extended-release tablet provides a treatment regimen that may help patients meet their weight loss goals."

BELVIQ XR is proven to be slowly absorbed in the body and last throughout the day. The 20 mg once-daily extended-release formulation is approved for use with a reduced-calorie diet and increased physical activity for chronic weight management in adults who have a body mass index (BMI) of 30 kg/m² or greater (obese), or BMI of 27 kg/m² or greater (overweight) with at least one weight-related medical condition, such as high blood pressure, high cholesterol or type 2 diabetes. It is not known if BELVIQ XR, when taken with other prescription, over-the-counter, or herbal weight-loss products, is safe and effective. It is not known if BELVIQ XR changes your risk of heart problems, stroke or death due to heart problems or stroke.

"We are pleased that BELVIQ XR is now available to patients and may provide them with a new option that can be used as part of their weight management armamentarium," said Amit Munshi, President and Chief Executive Officer, Arena Pharmaceuticals, Inc. "The launch of this new formulation is another example of Arena's success in supporting our collaborators."

"Eisai is committed to those living with obesity—a chronic, progressive disease that has serious health consequences," said Paul Hawthorne, Senior Vice President, Neurology Business Group, Eisai Inc. "We are excited to offer patients a once-daily option for chronic weight management that may help them achieve and sustain their weight loss goals."

For those who qualify, including those with Medicare Part D coverage (restrictions apply), Eisai will also offer a savings card, with two ways to save money on prescriptions. For more information about the program, patients can visit www.belviqxr.com or call 1(855) BELVIQ-1 (1-855-235-8471).

What are BELVIQ[®] and BELVIQ XR[®]?

BELVIQ[®] (lorcaserin HCl) CIV and BELVIQ XR[®] are FDA-approved prescription weight-loss medications that, when used with diet and exercise, can help some overweight (Body Mass Index [BMI] ≥ 27 kg/m²) adults with a weight-related medical problem, or obese (BMI ≥ 30 kg/m²) adults, lose weight and keep it off.

It is not known if BELVIQ or BELVIQ XR when taken with other prescription, over-the-counter, or herbal weight-loss products is safe and effective. It is not known if BELVIQ or BELVIQ XR changes your risk of heart problems, stroke, or death due to heart problems or stroke.

Important Safety Information

- 1 **Pregnancy:** Do not take if you are pregnant or planning to become pregnant, as weight loss offers no potential benefit during pregnancy and BELVIQ or BELVIQ XR may harm your unborn baby.
- 1 **Hypersensitivity Reactions:** Do not take if you are allergic to either of these medicines or any of their ingredients.
- 1 **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions:** Before using, tell your healthcare provider about all the medicines you take, especially medicines that treat depression, migraines, mental problems, or the common cold. These medicines may cause serious or lifethreatening side effects if taken with BELVIQ or BELVIQ XR. Call your healthcare provider right away if you experience agitation, hallucinations, confusion, or other changes in mental status; coordination problems; uncontrolled muscle spasms; muscle twitching; restlessness; racing or fast heartbeat; high or low blood pressure; sweating; fever; nausea; vomiting; diarrhea; or stiff muscles.
- 1 **Valvular heart disease:** Some people taking medicines like BELVIQ or BELVIQ XR have had heart valve problems. Call your healthcare provider right away if you experience trouble breathing; swelling of the arms, legs, ankles, or feet; dizziness, fatigue, or weakness that will not go away; or fast or irregular heartbeat. Before taking BELVIQ or BELVIQ XR, tell your healthcare provider if you have or have had heart problems.
- 1 **Changes in attention or memory:** BELVIQ or BELVIQ XR may slow your thinking. You should not drive a car or operate heavy equipment until you know how BELVIQ or BELVIQ XR affects you.
- 1 **Mental problems:** Taking too much BELVIQ or BELVIQ XR may cause hallucinations, a feeling of being high or in a very good mood, or feelings of standing outside your body.
- 1 **Depression or thoughts of suicide:** Call your healthcare provider right away if you notice any mental changes, especially sudden changes in your mood, behaviors, thoughts, or feelings, or if you have depression or thoughts of suicide.
- 1 **Low blood sugar:** Weight loss can cause low blood sugar in people taking medicines for type 2 diabetes, such as insulin or sulfonylureas. Blood sugar levels should be checked before and while taking BELVIQ or BELVIQ XR. Changes to diabetes medication may be needed if low blood sugar develops.
- 1 **Painful erections:** If you have an erection lasting more than 4 hours while on BELVIQ or BELVIQ XR, stop taking BELVIQ or BELVIQ XR and call your healthcare provider or go to the nearest emergency room right away.
- 1 **Slow heartbeat:** Both BELVIQ or BELVIQ XR may cause your heart to beat slower.
- 1 **Decreases in blood cell count:** BELVIQ or BELVIQ XR may cause your red and white blood cell counts to decrease.
- 1 **Increase in prolactin:** BELVIQ or BELVIQ XR may increase the amount of a hormone called prolactin. Tell your healthcare provider if your breasts begin to make milk or a milky fluid, or if you are a male and your breasts increase in size.
- 1 **Most common side effects of BELVIQ or BELVIQ XR:** Headache, dizziness, fatigue, nausea, dry mouth, constipation, cough, low blood sugar (hypoglycemia) in patients with diabetes, and back pain.
- 1 **Nursing:** BELVIQ or BELVIQ XR should not be taken while breastfeeding.
- 1 **Drug interactions:** Before taking BELVIQ or BELVIQ XR, tell your healthcare provider if you take medicines for depression, migraines, or other medical conditions, such as: triptans; medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, selective serotonin reuptake inhibitors, selective serotonin-norepinephrine reuptake inhibitors, monoamine oxidase inhibitors, or antipsychotics; cabergoline; linezolid (an antibiotic); tramadol; dextromethorphan (an over-the-counter (OTC) common cold/cough medicine); OTC supplements such as tryptophan or St. John's Wort; or erectile dysfunction medicines.

BELVIQ and BELVIQ XR are federally controlled substances (CIV) because they may be abused or lead to drug dependence.

For more information about BELVIQ or BELVIQ XR talk to your healthcare provider and see the full Product Information for BELVIQ or BELVIQ XR.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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 and follow us on [Twitter](#) and [LinkedIn](#).

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.

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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 and BELVIQ XR; 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 and BELVIQ XR; cash and revenues generated from BELVIQ and BELVIQ XR; 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 or BELVIQ XR 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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