December 19, 2016

Eisai and Arena Pharmaceuticals Announce Regulatory Approval of BELVIQ® (lorcaserin HCl) in Brazil

WOODCLIFF LAKE, N.J. and SAN DIEGO, Dec. 19, 2016 /PRNewswire/ -- Eisai Inc. and Arena Pharmaceuticals, Inc. (NASDAQ: ARNA) today announced that Eisai Laboratórios Ltda., a subsidiary of Eisai Inc., has received regulatory approval from the Brazilian Health Surveillance Agency (ANVISA) for BELVIQ® (lorcaserin HCl) for chronic weight management.

BELVIQ is approved in Brazil as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with a body mass index (BMI) of 30 kg/m^2 or greater (obese), or overweight patients with a BMI greater than or equal to 27 kg/m^2 in the presence of at least one weight-related comorbid condition such as high blood pressure, high cholesterol, cardiovascular disease, type 2 diabetes managed with oral hypoglycemic agents or sleep apnea. The product is expected to become available following review by Brazil's Medicines Market Regulation Board (CMED), which will trigger a $1 million milestone payment to Arena.

"Currently, more than half of the Brazilian population is overweight or obese and, without intervention, these numbers are projected to increase," said Shaji Procida, President and Chief Operating Officer, Eisai Inc. "This approval represents a new option for Brazilians who find it difficult to lose weight through diet and exercise alone. At Eisai, we remain committed to help address the needs of this patient population."

In addition to Brazil, BELVIQ is approved for weight management in the United States and South Korea. Lorcaserin is also approved in Mexico under the brand name VENESPRI® (lorcaserin HCl).

About BELVIQ® (lorcaserin HCl) CIV for Chronic Weight Management in the United States
BELVIQ is an FDA-approved prescription weight-loss medication that, when used with diet and exercise, can help some adults (body mass index [BMI] ≥27 kg/m^2) living with extra weight, with a weight-related medical problem, or adults living with obesity (BMI ≥30 kg/m^2), lose weight and keep it off.

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

For more information about BELVIQ in the United States, click here for the full Product Information or visit www.BELVIQ.com.

Important Safety Information for BELVIQ® in the United States

Pregnancy: Do not take BELVIQ if you are pregnant or planning to become pregnant, as weight loss offers no potential benefit during pregnancy and BELVIQ may harm your unborn baby.

Hypersensitivity: Do not take BELVIQ if you are allergic to lorcaserin hydrochloride or any of the ingredients in BELVIQ.

Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions: Before using BELVIQ, 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 life-threatening side effects if taken with BELVIQ. 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.

Valvular heart disease: Some people taking medicines like BELVIQ 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, tell your Healthcare Provider if you have or have had heart problems.

Changes in attention or memory: BELVIQ may slow your thinking. You should not drive a car or operate heavy equipment until you know how BELVIQ affects you.

Mental problems: Taking too much BELVIQ may cause hallucinations, a feeling of being high or in a very good mood, or feelings of standing outside your body.

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.

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. Changes to diabetes medication may be needed if low blood sugar develops.

Painful erections: If you have an erection lasting more than 4 hours while on BELVIQ, stop taking BELVIQ and call your Healthcare Provider or go to the nearest emergency room right away.

Slow heartbeat: BELVIQ may cause your heart to beat slower.

Decreases in blood cell count: BELVIQ may cause your red and white blood cell counts to decrease.

Increase in prolactin: BELVIQ 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.

Most common side effects in patients without diabetes: Headache, dizziness, fatigue, nausea, dry mouth, and constipation.

Most common side effects in patients with diabetes: Low blood sugar, headache, back pain, cough, and fatigue.

Nursing: BELVIQ should not be taken while breastfeeding.

Drug interactions: Before taking BELVIQ, 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 is a federally controlled substance (CIV) because it may be abused or lead to drug dependence.

For more information about BELVIQ®, talk to your Healthcare Provider and see the full Product Information.

About Eisai Laboratorios
Eisai Laboratórios Ltda. is a pharmaceutical company dedicated to providing new treatment options to patients and their

families living in Brazil. As a part of the global network of Eisai companies, it plays a key role in Eisai's effort to help improving the lives of patients and families worldwide.

Eisai Laboratórios Ltda. is a part of Eisai's Americas operations, which also include companies in Mexico, Canada and the United States. Eisai Laboratórios Ltda., located in São Paulo, Brazil, is a subsidiary of Eisai Inc. a company based in the United States.

About Eisai Inc.
At Eisai Inc., *human health care (hhc)* is our goal. We give our first thought 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 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.

For more information, visit Arena's website at www.arenapharm.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 the expected availability and commercialization of lorcaserin; the achievement of a milestone; the projected increase in the population that is overweight or obese; Eisai's commitment; Arena's focus, plans and strategy; the advancement and potential of Arena's clinical programs and collaborations; and activities with Eisai and other collaborators. 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 and developing drugs; the risk that we may need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; cash and revenues generated from BELVIQ, including the impact of competition; 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 lorcaserin may not be approved for marketing in a different formulation or in any other territory; 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; 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/eisai-and-arena-pharmaceuticals-announce-regulatory-approval-of-belviq-lorcaserin-hcl-in-brazil-300381261.html

SOURCE Eisai Inc.