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Eisai Co., Ltd.

U.S. FDA APPROVES BELVIQ XR[®], A ONCE-DAILY FORMULATION OF LORCASERIN FOR CHRONIC WEIGHT MANAGEMENT

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the U.S. Food and Drug Administration (FDA) has approved a New Drug Application (NDA) for BELVIQ XR[®], a once-daily formulation of lorcaserin hydrochloride (generic name, U.S. brand name: BELVIQ[®]) for chronic weight management. BELVIQ XR is scheduled for launch in autumn 2016.

BELVIQ XR is a sustained release formulation which enables once-daily treatment, increasing the convenience of administration compared to twice-daily BELVIQ tablets. This approval was based on clinical data that confirmed bioequivalence of once-daily 20 mg BELVIQ XR with twice-daily 10 mg BELVIQ tablets. Eisai believes BELVIQ XR will offer patients the potential benefits of the full FDA approved 20 mg dose in a simple once daily tablet.

This approval was obtained by Arena Pharmaceuticals, Inc. (Headquarters: California, United States, President and CEO: Amit D. Munshi, "Arena"), whom Eisai and its U.S. subsidiary Eisai Inc. have an exclusive licensing agreement with to commercialize lorcaserin hydrochloride.

BELVIQ was approved by the FDA in 2012 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 co-morbid condition, and has been available to patients in the United States since June 2013. In July 2016, lorcaserin hydrochloride was approved in Mexico under the brand name VENESPRI[®].

Through obtaining approval for BELVIQ XR, Eisai continues to make further contributions to address unmet medical needs in the clinical management of obesity and increase the benefits for patients and their families.

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[Notes to editors]

1. About lorcaserin hydrochloride (U.S. brand name: BELVIQ, “lorcaserin”)

Discovered and developed by Arena Pharmaceuticals, Inc., lorcaserin is a novel chemical entity that is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain. Activation of these receptors may help a person eat less and feel full after eating smaller amounts of food. Lorcaserin was approved in June 2012 by the U.S. Food and Drug Administration (FDA) 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 co-morbid condition, and was launched in the United States under the brand name BELVIQ in June 2013 after receiving a final scheduling designation from the U.S. Drug Enforcement Administration (DEA). Lorcaserin was approved in Mexico in July 2016 with the same indication as for the United States.

In addition, the agreement granting Eisai exclusive rights to market and distribute lorcaserin in 21 countries throughout the Americas, was expanded in November 2013 to include most countries and territories worldwide, most notably the European Union, Japan and China (excluding South Korea, Taiwan, Australia, New Zealand and Israel).

The most common adverse reactions observed in multiple Phase III clinical studies on lorcaserin were headache, dizziness, fatigue, nausea, dry mouth and constipation in patients without diabetes, and hypoglycemia, headache, back pain, cough and fatigue in patients with diabetes. For further information on lorcaserin in the United States, including Important Safety Information (ISI), please visit the BELVIQ product website (<http://www.belviq.com>).

Furthermore, lorcaserin is currently being investigated in a cardiovascular outcomes trial conducted in multiple countries, including the United States, with 12,000 patients. The three primary outcome measures of the trial concern MACE (Major Adverse Cardiovascular Events including myocardial infarction, stroke and cardiovascular death), conversion to type 2 diabetes mellitus and MACE+ (including myocardial infarction, stroke, cardiovascular death and hospitalization due to unstable angina, heart failure, or any coronary revascularization), respectively. Topline results of the trial are expected in fiscal year 2018.

VENESPRI[®] and BELVIQ[®] are registered trademarks of Arena Pharmaceuticals GmbH.

2. About Worldwide Overweight and Obesity

In recent years, obesity has become a major global health problem, with more than 1.4 billion adults worldwide believed to be overweight and approximately 500 million of that number qualifying as obese. By region, around 170 million people in the United States and 150 million people in Europe are reported to fall into one or both categories, while in Asia, the overweight and obese population includes an estimated 100 million people in China and a further 25 million people in Japan.