No.15-82

December 1, 2015
Eisai Co., Ltd.

U.S. FDA ACCEPTS NDA FOR ONCE-DAILY FORMULATION OF ANTIOBESITY AGENT BELVIQ®

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the U.S. Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for a once-daily formulation of its antiobesity agent BELVIQ® (U.S. brand name, generic name: lorcaserin hydrochloride, "lorcaserin") which has the potential to offer patients the convenience of once-daily treatment.

Acceptance of the application indicates that the FDA has found the submission to be sufficiently complete to review and that the FDA will begin conducting its assessment of the application. This NDA was submitted to the FDA by Arena Pharmaceuticals, Inc. (Headquarters: California, United States, Interim CEO: Harry F. Hixson), with whom Eisai and its U.S. subsidiary Eisai Inc. have a marketing and supply agreement. Upon FDA approval, Eisai will be responsible for commercializing the once-daily formulation in the United States.

A twice-daily formulation of lorcaserin 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/m^2 or greater (obese) or 27 kg/m^2 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 under the brand name BELVIQ since June 2013.

Through BELVIQ, Eisai will continue to make further contributions to address unmet medical needs that exist in the clinical management of obesity and increase the benefits for patients and their families.

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[Notes to editors]

1. About BELVIQ (lorcaserin hydrochloride)

Discovered and developed by Arena Pharmaceuticals, Inc., BELVIQ is a new 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. BELVIQ 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/m^2 or greater (obese) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related co-morbid condition, and was launched in the United States in June 2013 after receiving a final scheduling designation from the U.S. Drug Enforcement Administration (DEA).

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 BELVIQ, including Important Safety Information (ISI), please visit the BELVIQ product website (http://www.belviq.com).

Furthermore, BELVIQ 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.

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.