

No.16-70

October 4, 2016 Eisai Co., Ltd.

BELVIQ XR[®] - A NEW ONCE-DAILY FORMULATION OF BELVIQ[®] FOR CHRONIC WEIGHT MANAGEMENT NOW AVAILABLE IN THE UNITED STATES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has launched BELVIQ XR[®] 20mg tablets, a new once-daily formulation of BELVIQ[®] (generic name: lorcaserin hydrochloride) for chronic weight management in the United States.

BELVIQ XR is an extended release formulation proven to be slowly absorbed in the body and to last throughout the day. The availability of once-daily BELVIQ XR (20mg) in a single tablet provides patients with another dosing option in addition to the conventional twice-daily BELVIQ (10mg).

Approval for twice-daily BELVIQ was obtained in the United States 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 from the U.S. Food and Drug Administration (FDA) in 2012 by Arena Pharmaceuticals, Inc. (Headquarters: California, United States, President and CEO: Amit D. Munshi, "Arena"), whom Eisai and Eisai Inc. have an exclusive licensing agreement with to commercialize lorcaserin hydrochloride, and was launched in June 2013. Once-daily BELVIQ XR was approved with the same indication by the FDA in July 2016.

"Eisai is committed to efforts in research and development, disease awareness as well as other activities in order to address the diverse needs of to those living with obesity - a chronic, progressive disease that has serious health consequences," said Paul Hawthorne, Senior Vice President, Americas Neurology Business Unit, 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."

Through the launch of 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.

Media Inquiries: Public Relations Department, Eisai Co., Ltd. +81-(0)3-3817-5120



Eisai Co., Ltd.

[Notes to editors]

1. About lorcaserin hydrochloride (U.S. brand name: BELVIQ, BELVIQ XR "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). 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). Lorcaserin was approved in Mexico under the brand name VENESPRI[®] in July 2016 with the same indication as for the United States. Furthermore, the agent is currently undergoing regulatory review in Brazil.

Once-daily BELVIQ XR was approved with the same indication by the FDA in July 2016.

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 (<u>http://www.belviq.com</u>).

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. (Eisai's internal estimates)