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Eisai Co., Ltd.

## **ANTI-OBESITY AGENT VENESPRI® (LORCASERIN) APPROVED IN MEXICO** *FIRST COUNTRY IN LATIN AMERICA TO APPROVE LORCASERIN*

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its pharmaceutical sales subsidiary in Mexico, Eisai Laboratorios, S. de R.L. de C.V. (Location: Mexico City, "Eisai Mexico") has received approval for the antiobesity agent VENESPRI® (lorcaserin hydrochloride, U.S. brand name: BELVIQ®, "lorcaserin") 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<sup>2</sup> or greater (obese) or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related co-morbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes) by the Federal Commission for the Protection Against Sanitary Risk (COFEPRIS), the Mexico regulatory authority. Mexico marks the first country in Latin America where lorcaserin is approved. Lorcaserin will be marketed in Mexico under the brand name VENESPRI.

Discovered and developed by Arena Pharmaceuticals, Inc. (Headquarters: California, United States, President and CEO: Amit D. Munshi, "Arena"), 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. Eisai's U.S. subsidiary Eisai Inc. has an exclusive licensing agreement with Arena to commercialize lorcaserin in most countries and territories worldwide, including Europe, Japan and China (excluding South Korea, Taiwan, Australia, New Zealand and Israel).

In 2014, Mexico's pharmaceutical market was worth 11.3 billion U.S. dollars, making it the 16th biggest pharmaceutical market in the world, and the third biggest in Latin America after Brazil and Venezuela.<sup>1</sup> In 2019, Mexico's pharmaceutical market is expected to grow to a scale of 13.4 billion U.S. dollars.<sup>2</sup> In August 2011, Eisai established Eisai Mexico, which currently markets the anticancer agents Lenvima®, Halaven® and Gliadel®. Regarding antiepileptic agents, Eisai Mexico has received approval for Inovelon® and has submitted Fycompa® for regulatory review.

Eisai is committed to delivering innovative new treatments to patients in Mexico while enhancing its product lineup as it seeks to further increase the benefits it provides to patients and their families in the country.

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## [Notes to editors]

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

Discovered and developed by Arena Pharmaceuticals, Inc., lorcaserin 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. 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/m<sup>2</sup> or greater (obese) or 27 kg/m<sup>2</sup> 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 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 and Mexico, 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.

### **3. About Eisai Mexico**

Eisai established Eisai Laboratorios, S. de R.L. de C.V. (Eisai Mexico) in August 2011 in Mexico City as a direct subsidiary of Eisai's U.S. subsidiary Eisai Inc. Mexico is ranked as the fifth largest pharmaceutical market in the Americas behind the United States, Canada, Brazil and Venezuela and the 16th largest in the world.<sup>1</sup>

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