

ANTI-OBESITY AGENT BELVIQ[®] APPROVED IN BRAZIL

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its pharmaceutical sales subsidiary in Brazil, Eisai Laboratórios Ltda. (Location: São Paulo, "Eisai Brazil") has received approval for the anti-obesity agent BELVIQ[®] (lorcaserin hydrochloride, "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/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related co-morbid condition (e.g., high blood pressure, high cholesterol, cardiovascular disease, type 2 diabetes managed with oral hypoglycemic agents or sleep apnea) by the Brazil National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária: ANVISA), the regulatory authority in Brazil. Brazil marks the second country in Latin America to approve lorcaserin after Mexico.

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 and its U.S. subsidiary Eisai Inc. have an exclusive licensing agreement with Arena to commercialize lorcaserin in most countries and territories worldwide, including the Americas, Europe, Japan and China (excluding South Korea, Taiwan, Australia, New Zealand and Israel).

In 2015, the Brazilian pharmaceutical market was worth US\$25.6 billion (approximately 2.6 trillion yen), representing the largest market in Latin America and 8th largest market in the world.¹ Eisai established Eisai Brazil in April 2011 as its first pharmaceutical sales company in Latin America, which currently markets the anticancer agent Halaven[®]. In addition to lorcaserin, the anticancer agents Lenvima[®] and Gliadel[®] as well as the antiepileptic agents Fycompa[®] and Inovelon[®] have been approved in Brazil.

Eisai is committed to delivering innovative new treatments to patients in Brazil 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 (generic name: lorcaserin hydrochloride, brand name: BELVIQ)

Discovered and developed by Arena, 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/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 in June 2013 after receiving a final scheduling designation from the U.S. Drug Enforcement Administration (DEA). In July 2016, lorcaserin was approved in Mexico as VENESPRI[®] with the same indication as for the United States. Also in July 2016, a once-daily formulation of lorcaserin was approved in the United States by the U.S. FDA as BELVIQ XR[®] with the same indication.

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>).

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)

3. About the Brazilian Healthcare System

The Brazilian constitution defines health care as a right for all citizens and in principle, all citizens can receive public health care for free through the publicly funded Sistema Único de Saúde (SUS) which was introduced in 1990. As the medicines and medical services provided through SUS are limited due to its financial difficulties, around a quarter of the population pays for private health insurance which covers approximately 50% of all medical expenses.

4. About Eisai Laboratórios Ltda. (Eisai Brazil)

In April 2011, Eisai established Eisai Brazil as a pharmaceutical sales subsidiary in São Paulo, the capital city of São Paulo state. Eisai Brazil is a subsidiary of Eisai's U.S. subsidiary Eisai Inc.

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