No.18-106

December 17, 2018
Eisai Co., Ltd.

EISAI SIGNS COLLABORATION AGREEMENT FOR ANTI-OBESITY AGENT LORCASERIN IN BRAZIL WITH EUROFARMA

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has entered into an agreement to grant exclusive development and marketing rights for its anti-obesity agent lorcaserin hydrochloride (generic name, product name in the United States: BELVIQ®, product name for once-daily formulation in the United States: BELVIQ XR®, "lorcaserin") in Brazil to Eurofarma Laboratórios S.A. (Headquarters: Sao Paulo, Brazil, President: Maurizio Billi, "Eurofarma").Under this agreement, Eisai will supply Eurofarma with lorcaserin. Eisai will receive a one-time contractual payment and is eligible for milestone payments for sales in Brazil.
In October 2018, Eisai signed an agreement to grant exclusive development and marketing rights for lorcaserin in 17 countries* in Latin America and the Caribbean, excluding Brazil.

Lorcaserin is an anti-obesity agent that is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain. Lorcaserin was approved in 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. Lorcaserin was approved in Brazil with the same indication as for the United States in December 2016.

By granting exclusive development and marketing rights for lorcaserin in Brazil to Eurofarma as well, Eisai aims to leverage Eurofarma's strong business foundation throughout Latin America to accelerate the delivery of lorcaserin to more patients.

*17 countries: Argentina, Belize, Bolivia, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay, Venezuela

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[Notes to editors]

1. About lorcaserin hydrochloride (product name in the United States: BELVIQ, product name for once-daily formulation in the United States: BELVIQ XR, "lorcaserin")

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. 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^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 under the brand name BELVIQ in June 2013 after receiving a final scheduling designation from the U.S. Drug Enforcement Administration (DEA). In addition, lorcaserin has been made available in South Korea, Taiwan and Israel via a third-party distributor. Lorcaserin was approved in Mexico in July 2016 and in Brazil in December 2016, with the same indication as for the United States. Furthermore, BELVIQ XR, a once-daily formulation of lorcaserin aiming to increase convenience of administration for patients, was approved in the United States in July 2016. In January 2017, Eisai acquired all of Arena's rights to develop and market lorcaserin.

In August 2018, in a cardiovascular outcomes trial (CAMELLIA-TIMI61) of lorcaserin, a post-marketing clinical trial evaluating safety as the primary objective, it was confirmed that lorcaserin did not increase the incidence of major adverse cardiovascular events (MACE: defined as cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) compared to placebo, and the primary safety objective was met. Regarding the primary efficacy endpoint of incidence of MACE+ (consisting of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, hospitalization due to unstable angina, heart failure or coronary revascularization), statistical non-inferiority compared to placebo was confirmed for lorcaserin. Data on the effect of lorcaserin on prevention and remission of type-2 diabetes mellitus was announced in October 2018.

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.

2. About Overweight and Obesity in Brazil (Eisai's internal estimates)

In recent years, obesity has become a major global health problem, with more than 1.4 billion adults worldwide believed to be overweight (BMI of 25 kg/m^2 or greater) and approximately 500 million of that number qualifying as obese (BMI of 30 kg/m^2 or greater). 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.

In Brazil as well, obesity is becoming a serious health issue, with the prevalence of obesity among adults being 22% of the overall population.[1] Due to changes in lifestyle and other factors, the incidence of obesity is expected to continue to increase.

3. About Eurofarma Laboratórios S.A. (Eurofarma)

Founded in 1972, Eurofarma is one of the largest pharmaceutical companies in Brazil and is present in 20 countries in South and Central America, the Caribbean and Africa. In addition to Brazil, it has its own operations in Argentina, Bolivia, Chile, Colombia, Ecuador, Guatemala, Paraguay, Peru and Uruguay, and also sells products in Belize, Costa Rica, Dominican Republic, El Salvador, Honduras, Mexico, Nicaragua, Panama, Venezuela and Mozambique. Eurofarma's capabilities span from research and development to clinical trial execution to marketing and sales of in-licensed and wholly owned products. Eurofarma's mission is to promote access to health and quality of life with reasonably priced treatments while maintaining a profitable operation to assure sustainable growth and share the value generated with employees and society. To learn more about Eurofarma, please visit www.eurofarma.com.br

[1] WHO Global Health Observatory data: http://apps.who.int/gho/data/node.main.BMI30C?lang=en