No.18-68

July 31, 2018
Eisai Co., Ltd.

EISAI SIGNS COLLABORATION AGREEMENT FOR ANTI-OBESITY AGENT LORCASERIN IN CHINA WITH CY BIOTECH

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 China (including Hong Kong and Macao) to CY Biotech (Headquarters: Taipei, Taiwan, "CYB").
Under this agreement, Eisai will supply CYB with lorcaserin. Eisai will receive a one-time contractual payment and milestone payments dependent upon acquisition of regulatory approval. In addition, Eisai has the option rights to co-promote lorcaserin with CYB in China (excluding Hong Kong and Macao), as well as the option rights to market lorcaserin in Hong Kong and Macao.

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 in June 2013. Lorcaserin was approved in Mexico in July 2016 and in Brazil in December 2016, with the same indication as for the United States. In Taiwan, lorcaserin was developed by CYB, who obtained approval in July 2017 and launched lorcaserin in Taiwan in October 2017.

By entering into this agreement with CYB, which already has a track record in developing and marketing lorcaserin in Taiwan, Eisai is aiming to accelerate the delivery of lorcaserin to patients in these regions.

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

[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., 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/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 via a third-party distributor from 2015. 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.

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.

A cardiovascular outcomes trial conducted in multiple countries, including the United States, with 12,000 patients found that long-term treatment with lorcaserin does not increase incidence of MACE (Major Adverse Cardiovascular Events including myocardial infarction, stroke and cardiovascular death), and the primary safety objective of the trial was met. In addition, regarding the incidence of MACE+ (consisting of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, hospitalization due to unstable angina, heart failure or coronary revascularization) which was the primary efficacy endpoint, although statistical superiority to placebo was not met, the results successfully confirmed statistical non-inferiority for lorcaserin. In this trial, lorcaserin also demonstrated an improvement in multiple cardiovascular risk factors including blood pressure, lipids, blood glucose and renal function as well as a reduction in conversion to type 2 diabetes mellitus (T2DM) in patients without diabetes. Furthermore, in additional subgroup analyses, on a background of lifestyle modification, it was observed that lorcaserin improved long-term weight loss compared to placebo, including in subpopulations with T2DM and obstructive sleep apnea.

2. About CY Biotech Company Ltd.

CY Biotech Company Ltd. (CYB) is a pharmaceutical company established in April 2011 with its headquarters in Taiwan. In 2012, CYB launched a wholly-owned subsidiary Chuang Yi Trading Limited in Shanghai. CYB obtained the exclusive rights for marketing and distributing lorcaserin in Taiwan and has been marketing lorcaserin in Taiwan since 2017. Aiming to be an innovative leader in self-paid pharmaceutical and health products with a wide range of indications, CYB is striving to improve the Quality of Life (QOL) of patients in Greater China.