

LORCASERIN MEETS PRIMARY ENDPOINT AND CONFIRMS PROOF-OF-CONCEPT AS POTENTIAL AID FOR SMOKING CESSATION IN INVESTIGATIONAL PHASE II CLINICAL STUDY

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that in a Phase II clinical study investigating the serotonin 2C receptor agonist lorcaserin hydrochloride (U.S. brand name: BELVIQ®; "lorcaserin") as a potential aid for smoking cessation conducted by Arena Pharmaceuticals, Inc. (Headquarters: California, United States; President & CEO: Jack Lief, "Arena") and its U.S. subsidiary Eisai Inc., lorcaserin demonstrated a statistically significant increase in the study's primary endpoint of continuous quit rate compared to placebo, thus confirming proof-of-concept. The results of this study are the first clinical evidence that a selective serotonin 2C agonist has a potential as a treatment for smoking cessation. Detailed results of the study are expected to be presented at an upcoming scientific meeting.

The study was a randomized, double-blind, placebo-controlled trial designed to assess the efficacy of lorcaserin as an aid to smoking cessation. In the study, 603 active smokers were randomized 1:1:1 to one of three treatment arms consisting of either lorcaserin 10 mg once daily, lorcaserin 10 mg twice daily, or placebo. Patients at baseline were dependent on nicotine and averaged at least 18 cigarettes per day. Patients received treatment for 12 weeks as well as smoking cessation counseling throughout the study. Patients were dosed for two weeks before attempting to quit around day 15 of the study.

The primary endpoint assessed the continuous quit rate during the last four weeks of the trial (weeks 9-12) as confirmed by the measurement of carbon monoxide. The continuous quit rate is defined as no reported smoking or other nicotine use and an end-expiratory exhaled carbon monoxide measurement less than or equal to ten parts per million. The primary endpoint was achieved by 5.6%, 8.7%, and 15.3% of patients in the placebo, lorcaserin 10 mg once daily and twice daily groups, respectively, with the lorcaserin twice daily group demonstrating a statistically significantly higher continuous quit rate than placebo (p-value 0.003 and odds ratio of 3.02).

In addition to smoking cessation efficacy, a reduction in bodyweight was also observed. Change in bodyweight from baseline to week 12 was one of the secondary endpoints and a statistically significant difference was observed between lorcaserin twice daily and placebo groups (-0.98 kg and -0.01 kg, respectively, p-value = 0.0004).

In this trial, the most common adverse events were headache, nausea, constipation, dizziness and dry mouth, and the adverse event profile observed in the trial was similar to that observed in previous trials of lorcaserin.

Smoking is recognized as one of the greatest global public health challenges but unfortunately millions of people around the world continue to smoke and find it hard to quit. Eisai will further evaluate these results and continue to make efforts in order to contribute to the field of smoking cessation treatment.

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[Notes to editors]

1. About Smoking in the United States

According to the US Department of Health and Human Services, the epidemic of smoking-caused disease in the 20th Century ranks among the greatest American public health catastrophes. In the United States, more than 40 million adults smoke, resulting in smoking attributable economic costs estimated for the years 2009-2012 to be approximately \$300 billion. In 2014, nearly 500,000 American adults who smoke are expected to die prematurely. Smoking is also a global issue that results in more than 5 million deaths worldwide per year.

2. About Lorcaserin Hydrochloride (U.S. brand name: BELVIQ)

Lorcaserin hydrochloride ("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). 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. In addition, an 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 BELVIQ, including Important Safety Information (ISI), please visit the BELVIQ product website (<http://www.belviq.com>).