No.13-26

May 8, 2013
Eisai Co., Ltd.

PUBLICATION IN FEDERAL REGISTER TOMORROW MOVES BELVIQ® CLOSER TO LAUNCH

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that U.S. Drug Enforcement Administration (DEA) has placed antiobesty agent BELVIQ® (lorcaserin hydrochloride) into Schedule IV of the Controlled Substance Act. This information is expected to be published in the Federal Register on May 8 (local U.S. time), with an effective date of June 7, 2013. Eisai's U.S. subsidiary Eisai Inc. will launch the drug as soon as possible following the effective date.

BELVIQ received approval from the U.S. Food and Drug Administration (FDA) on June 27, 2012 (U.S. local time), 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, or 27 kg/m^2 or greater in the presence of at least one weight-related co-morbid condition. BELVIQ is the first new chemical entity to be approved as an antiobesity prescription drug in the United States in 13 years.

BELVIQ is a new chemical entity discovered and developed by Arena Pharmaceuticals, Inc. It is believed to act as a serotonin receptor agonist that selectively activates the serotonin 2C receptor in the brain and is believed to suppress food intake and promote weight loss. The exact mechanism of action is not known. BELVIQ demonstrated sustained weight-loss results in the appropriate patients as an adjunct to a reduced-calorie diet and increased physical activity. Furthermore, obese clinical trial patients with type 2 diabetes were reported to achieve statistically significant reduction both in HbA1c (hemoglobin A1c) and fasting glucose. The recommended dosage for BELVIQ is one 10 mg pill twice daily with no dose titration necessary, which is an added benefit that is also expected to improve patient drug compliance.

The Phase III clinical trial program cited in the application submitted to the U.S. FDA evaluated approximately 7,800 patients, which demonstrated that BELVIQ along with diet and exercise was more effective than diet and exercise alone at helping patients lose 5% or more of body weight after one year and managing the weight loss for up to two years.

In clinical trials, the most common adverse reactions (greater than 5% and more common than with placebo) for patients without diabetes were headache, dizziness, fatigue, nausea, dry mouth, and constipation and, for patients with diabetes, were hypoglycemia, headache, back pain, cough, and fatigue.

According to the U.S. Centers for Disease Control and Prevention, over two thirds of adults in the United States are either overweight or obese, with the percentage of obese people more than doubling (from approximately 15% to 36%) between 1980 and 2010. Being obese or overweight may be accompanied by other co-morbid conditions such as diabetes, dyslipidemia and hypertension, with the increase in the obese and overweight population constituting a major social problem.

Through the launch of BELVIQ, Eisai is committed to providing a new treatment option for weight management as it seeks to make further contributions to address the unmet medical needs that exist in the medical management of obesity and increase the benefits provided to patients and their families.

[Please refer to the following notes for further information on BELVIQ, including a product outline, and an outline of the BELVIQ Phase III clinical trial program.]

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

[Notes to editors]

1. About BELVIQ® (lorcaserin hydrochloride)

BELVIQ®, discovered and developed by Arena Pharmaceuticals, Inc., is a new chemical entity that is believed to decrease food consumption and promote satiety by selectively activating 2C receptors in the brain. Activation of these receptors may help a person eat less and feel full after eating smaller amounts of food. BELVIQ was approved by the U.S. Food and Drug Administration (FDA) in June 2012 as the first prescription weight-loss treatment to receive approval in the United States in 13 years. Eisai Co., Ltd.'s U.S. subsidiary Eisai Inc. has been granted exclusive marketing and supply rights for BELVIQ in 20 countries throughout the Americas, including Mexico, Brazil, and Canada, in addition to the United States.

2. Product Outline (U.S.)

1) Product Name: BELVIQ®
2) Generic Name: lorcaserin hydrochloride
3) Dosage Form and Strengths: 10 mg film-coated tablets
4) Indications and Usage:
   BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults 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 comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes).

   Limitations of Use:
   - The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss, including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations, have not been established.
   - The effect of BELVIQ on cardiovascular morbidity and mortality has not been established.
5) Dosage and Administration:
   The recommended dose of BELVIQ is 10 mg administered orally twice daily. Do not exceed recommended dose.
   BELVIQ can be taken with or without food.
   Response to therapy should be evaluated by week 12. If a patient has not lost at least 5% of baseline body weight, discontinue BELVIQ, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

3. BELVIQ® Phase III Clinical Trial Program Outline

The BELVIQ Phase III clinical trial program consisted of three double-blind, randomized, placebo-controlled trials, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus), and enrolled approximately 7,800 patients. All three trials included a standardized program of diet, moderate exercise and behavioral counseling for both the placebo and BELVIQ groups.

BLOOM and BLOSSOM evaluated the safety and efficacy of BELVIQ versus placebo in non-diabetic, obese (BMI of 30 to 45 kg/m^2) adult patients (18-65 years old) and non-diabetic overweight (BMI 27 to 29.9 kg/m^2) patients who have at least one weight-related co-morbid condition. BLOOM evaluated BELVIQ versus placebo in 3,182 patients over a two-year treatment period, while BLOSSOM evaluated BELVIQ versus placebo in 4,008 patients over a one-year treatment period. In both the BLOOM and BLOSSOM trials, BELVIQ produced statistically significant and clinically meaningful weight loss compared to placebo. The most common adverse events (greater than 5% and more common than with placebo) in these trials were headache, dizziness, fatigue, nausea, dry mouth, and constipation. Pooled data from BLOOM and BLOSSOM were presented at the American Diabetes Association's 70th Scientific Sessions in June 2010. BLOOM data was also published in the July 15, 2010 issue of the *New England Journal of Medicine*.

BLOOM-DM evaluated BELVIQ versus placebo in 604 obese and overweight adult patients with type 2 diabetes. The top-line results of the trial demonstrated that BELVIQ helped obese and overweight patients with type 2 diabetes achieve statistically significant weight loss as well as reduction both in HbA1c and fasting glucose, compared to placebo. The most commonly reported adverse events were hypoglycemia, headache, back pain, cough, and fatigue.