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Eisai Co., Ltd.

FDA ISSUES COMPLETE RESPONSE LETTER FOR LORCASERIN NEW DRUG APPLICATION

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that the U.S. Food and Drug Administration (FDA) issued a complete response letter regarding the New Drug Application (NDA) of Arena Pharmaceuticals, Inc. (Headquarters: California, United States, President & CEO: Jack Lief, “Arena”) for lorcaserin (generic name), a potential treatment for weight management currently under review in the United States.

Lorcaserin is the subject of an exclusive licensing agreement concluded between Eisai's U.S. Subsidiary Eisai Inc. and Arena Pharmaceuticals GmbH, the wholly-owned Swiss subsidiary of Arena concerning its commercialization in the United States. Lorcaserin, which Arena discovered and has developed, is intended for weight management, including weight loss and maintenance of weight loss, in patients who are obese (Body Mass Index, BMI≧30) or patients who are overweight (BMI≧27) and have at least one weight-related co-morbid condition.

In the complete response letter, the FDA outlined the non-clinical and clinical reasons for their decision. The non-clinical issues identified by the Agency are the safety issues related to the rat carcinogenicity study. With respect to the clinical reasons, the FDA recommended that Arena submit the final study report of the BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial.

It is an important step for Arena and Eisai toward the FDA’s approval of lorcaserin. Arena will meet with the FDA to obtain further clarity on the approval path and timeline. Arena and Eisai are committed to bringing a new treatment option to patients who need to manage their weight. The two companies will work closely with the FDA to address the comments outlined in the complete response letter.

A complete response letter is issued by the FDA’s Center for Drug Evaluation and Research when the review period for a drug is complete and the application is not yet ready for approval.

[Please refer to the following notes for information on lorcaserin, the lorcaserin NDA and BLOOM-DM Trial]

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[Notes to editors]

1. About Lorcaserin NDA (New Drug Application)

The lorcaserin new drug application is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase III clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years.

2. About Lorcaserin

Lorcaserin is a new chemical entity that is believed to act as a specific and selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area believed to be involved in the control of appetite and metabolism. Arena has patents that cover lorcaserin in the United States and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.

3. About BLOOM-DM Trial

The BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial evaluated lorcaserin versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes mellitus. The trial is complete and Arena expects to have a completed study report by the end of the year.