Eisai Co., Ltd.

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Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

Eisai Submits NDA Application of KES524 for Obesity Management in Japan

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) today announced that the company submitted an application to manufacture and distribute KES524 (generic name: sibutramine hydrochloride monohydrate), which the company had been developing in Japan for obesity management, to the Ministry of Health, Labour, and Welfare (MHLW).

Sibutramine, an obesity management treatment based on the mode of action of serotonin and noradrenalin reuptake inhibition in the central nervous system, is approved in 83 countries worldwide. In Japan, Eisai has the rights to develop and market KES524 exclusively under the contract with Abbott.

In a multi-center randomized double blind placebo controlled Phase III study conducted in Japan, 342 obese patients received either KES524 or placebo for 52 weeks.
The study demonstrated that KES524, compared with placebo, significantly improved the primary endpoints of change in bodyweight, and percent change in bodyweight, as well as the secondary endpoints of VFA (Visceral Fat Area), HbA1c (Hemoglobin A1c), TG (Triglyceride), and HDL-C (High-density lipoprotein cholesterol). The most common adverse events included constipation, dry mouth, and increase in heart rate, however, most of them were mild to moderate in degree and did not differ significantly from those observed in previous clinical studies in Japan and overseas.

Eisai is committed to enhancing the benefits of patients by providing a new treatment to manage obesity, while treatment needs for diseases such as obesity and metabolic syndrome, which is drawing attention these days, increase in Japan as well as in the U.S. and Europe.

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[Please see the attached for the information about the clinical trial]

Design of Phase III Double-Blind Comparative Study and the Results in Japan

1. Design

Subject:	342 obese patients (171 patients/arm)
Major Inclusion Criteria:	• BMI >= 25 Kg/m^2, VFA (Visceral Fat Area) >= 100 cm^2 • Diagnosed type 2 diabetes, 6.1% <= HbA_{1c} (Hemoglobin A1c) < 9.0% • Dyslipidemia TG >= 150 mg/dL and/or HDL-C < 40 mg/dL
Duration:	4-week screening, 52-week treatment, and 12-week following up
Administration:	KES524 (10 mg/day or increased to 15 mg/day if response was inadequate) or placebo
Primary Endpoints:	Change in bodyweight (kg) and percent change in bodyweight (%)
Secondary Endpoints:	VFA (Visceral Fat Area), HbA_{1c} (Hemoglobin A_{1c}), TG (Triglyceride) and HDL-C (High-density lipoprotein cholesterol), etc.

2. Results

The Phase III study demonstrated that KES524 significantly improved the primary endpoints of percent change in bodyweight by -5.00%, compared with -1.97% in the placebo arm. KES524 also significantly improved the other primary endpoints of change in bodyweight (kg) as well as the secondary endpoints of VFA (Visceral Fat Area), HbA1c (Hemoglobin A1c), TG (Triglyceride), and HDL-C (High-density lipoprotein cholesterol) compared with placebo. The most common adverse events included constipation, dry mouth, and increase in heart rate, however, most of them were mild to moderate in degree and did not differ significantly from those observed in previous clinical studies in Japan and overseas.