No.11-08

January 25, 2011
Eisai Co., Ltd.

PHASE III STUDY FOR SEVERE SEPSIS TREATMENT ERITORAN (E5564) DOES NOT MEET PRIMARY ENDPOINT

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today, based on the preliminary findings from the ACCESS (A Controlled Comparison of Eritoran and Placebo in Patients with Severe Sepsis) trial, that it will not submit marketing authorization applications for the severe sepsis treatment eritoran (generic name; E5564) to regulatory authorities in the United States, European Union (EU) and Japan by the end of fiscal year 2010 (year ending March 31, 2011), as previously planned. The decision was based on the fact that the trial, a Phase III study conducted in patients with severe sepsis, did not meet its primary endpoint of 28-day all-cause mortality. The company will continue its analysis of the eritoran clinical trial data and determine next steps.

The ACCESS trial was a global, randomized, double-blind, placebo-controlled trial that evaluated the potential of eritoran as a valuable new treatment for severe sepsis patients with a moderate-to-high risk of mortality as determined by baseline APACHE II (Acute Physiology and Chronic Health Evaluation II) scores from 21 to 37. APACHE II is a severity of illness scoring system commonly used in sepsis research. This scoring system and other severity of illness scoring systems are also used in intensive care units (ICU) to measure illness severity in severe sepsis patients.

Each year, severe sepsis causes approximately 215,000 deaths in the United States – as many as heart attacks, and nearly as many as lung, colorectal and breast cancers combined - with a mortality of approximately 30 percent. The incidence of severe sepsis in the European Union has been estimated at 90.4 cases per 100,000 population, with a mortality of 36 percent. The incidence of severe sepsis in Japan is estimated at more than 380,000 cases per year.

Eisai' s remains committed to the development of eritoran in line with the company's *human health care (hhc)* mission, which is to address unmet medical needs and increase benefits to patients and their families.

[Please refer to the following notes for further information on the ACCESS trial and APACHE II]

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[Notes to editors]

1. **About the ACCESS Trial**

   The ACCESS trial was a global, randomized, double-blind, placebo-controlled trial that evaluated the potential of eritoran as a treatment for severe sepsis. The trial targeted severe sepsis patients with a moderate-to-high risk of mortality as determined by baseline APACHE II (Acute Physiology and Chronic Health Evaluation II) scores from 21 to 37. The purpose of the study was to evaluate the 28 day all-cause mortality risk of eritoran versus placebo.

2. About APACHE II

   APACHE II (Acute Physiology and Chronic Health Evaluation II) is a scoring system that measures severity of illness and is predominantly used in severe sepsis research and intensive care units (ICU). Acute physiology score is the sum of 12 individual variable points: core temperature, mean arterial pressure, heart rate, respiratory rate, oxygenation, arterial pH, serum Na, serum K, serum creatinine, hematocrit, white blood cell count, Glasgow Coma Score (GCS).

   APACHE II score= acute physiology score + age points + chronic health points. Minimum score = 0; Maximum score = 71. Increasing score is associated with increasing risk of hospital death.