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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.

FOR IMMEDIATE RELEASE
No.10-10
March 26, 2010

Eisai Co., Ltd.

Eisai to Continue Eritoran (E5564) Phase III Severe Sepsis Trial

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that an independent Data Monitoring Committee (DMC), which met on March 25 (United Kingdom local time), has recommended the Company continue enrolment to the preset goal of 2,000 patients in the Phase III ACCESS (**A C**ontrolled **C**omparison of **E**ritoran and Placebo in Patients with **S**evere **S**epsis) trial, an Eisai global clinical development programme of the investigational compound eritoran (E5564) for severe sepsis. This recommendation was made based on a planned interim analysis evaluating safety and efficacy data from the ACCESS trial for the first 1,500 patients. In addition, the DMC did not express safety concerns that would warrant stopping the trial at this time.

In accordance with the DMC's recommendation, Eisai will continue enrolment to the planned goal of 2,000 patients in the trial.

Sepsis is a serious condition with an extreme systemic inflammatory response to infection. In severe cases, the mortality is very high due to the onset of septic shock, disseminated intravascular coagulation and organ dysfunction lead to high mortality. With few treatment options currently available, it is estimated that over 200,000 patients lose their life to severe sepsis in the United States each year.

Eritoran is an endotoxin antagonist discovered and developed by Eisai. By blocking endotoxins released from bacteria from binding to toll-like receptor 4 (TLR4), the compound inhibits the transduction of receptor signals triggered by the activation of TLR4. As a result, eritoran inhibits the release of inflammatory cytokines and suppresses the onset of septic symptoms.

Eisai is pursuing the clinical development of eritoran with the aim of addressing the unmet medical needs of severe sepsis patients for whom the mortality is very high. In accordance with the DMC's recommendation, Eisai will continue its efforts to enrol patients in the ACCESS trial with the hope of delivering eritoran to patients and healthcare professionals around the world in a timely manner.

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