No.13-70

November 29, 2013
Eisai Co., Ltd.

EISAI PRODUCT CREATION SYSTEMS (EPCS) UNDERGOES TRANSFORMATION WITH AIM OF FURTHER FOCUSING AND STRENGTHENING PRODUCT CREATION CAPABILITIES

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the company's research and development organization, Eisai Product Creation Systems (EPCS), has undergone a transformation with the aim of further focusing and strengthening its product creation capabilities. In order to fulfill its sole mission of ensuring that innovative new drugs that meet unmet medical needs are made available to patients as early as possible, EPCS has flexibly implemented organizational changes deemed necessary according to the progress of Eisai's development pipeline. The changes will allow Eisai to better prioritize and define its product creation activities by creating a leaner organizational structure that will more efficiently drive forward high-priority projects, increase focus on next-generation products and investigational compounds, and enhance the pursuit of innovation during development and discovery.
The major changes are as follows:

1. Function Optimization of Product Creation Units (PCUs) and Strengthening of Chief Clinical Officer (CCLO) Function
   To reflect Eisai's increased focus on key drug discovery areas, EPCS has undergone a shift in its structure. Previously, EPCS had a centralized management model within a single Core Function Unit (CFU) for clinical support functions worldwide. The new model has transferred those management responsibilities to other PCUs/CFUs in order to streamline communications and decision making. Other key clinical support functions such as those for statistical analysis and clinical pharmacology have been placed under the direct jurisdiction of the CCLO in an effort to further improve clinical success rates. The former Scientific & Operational Clinical Support (SOCS) CFU has also been dissolved as part of these changes.
   Additionally, in regard to drug discovery in the area of neuroscience at Eisai's EMEA* Knowledge Centre (EKC) in the United Kingdom, focus on the Open Innovation function, which primarily conducts joint research with University College London, has been increased, while the EKC's medicinal chemistry function has been dissolved.

2. Reorganization of Process Development Functions (Establishment of Biopharmaceutical Development Department)
   To support advancements in Eisai's development pipeline, functions for small-molecule process development have been consolidated in Japan (Kashima, Tsukuba) and India (Vizag), while the related functions at the Andover site in the United States have been dissolved. Andover will continue to serve as the discovery research hub in the United States.
   At the same time, in order to further strengthen and promote development of biopharmaceuticals as next-generation drugs, the biopharmaceutical development functions that had been divided between research sites in the United States (Exton, Andover) have been consolidated into the newly established Biopharmaceutical Development Department, which is located at the Exton site.

The reorganizations will result in the reduction of approximately 130 positions in Europe and the United States.

* EMEA: Europe, the Middle East, Africa and Oceania

[Please refer to the following notes for further information on Eisai Product Creation Systems.]

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

[Notes to editors]

1. About Eisai Product Creation Systems (EPCS)

The Eisai Group defines its research and development (R&D) activities as Product Creation in accordance with its mission to ensure that innovative drugs are delivered to patients as early as possible. The Group's R&D organization, Eisai Product Creation Systems (EPCS), combines venture-like productivity and speed with the knowledge resources of a global pharmaceutical company so as to establish a system that shortens development timelines, in turn helping to realize the early creation of innovative new drugs to treat diseases for which sufficient treatment does not yet exist.

EPCS encompasses Production Creation Units (PCUs), Core Function Units (CFUs), and the Product Creation Headquarters. The PCUs, which comprise five units, including units specializing in oncology and neurology, are wholly responsible for conducting the series of processes ranging from discovery of innovative drug candidates through regulatory filing and approval. The CFUs, which will now comprise five units, take full responsibility for obtaining and maintaining a highly competitive edge in preclinical and clinical operations, technology, regulatory affairs and other shared core functions as well as promoting new drug development in cooperation with the PCUs.

Meanwhile, the Product Creation Headquarters are responsible for formulation of product creation structural strategies, corporate portfolio management, and the promotion of product creation activities. Through this EPCS system, the Eisai Group is striving to build an organization comprising autonomous units with clearly defined responsibilities and which are specialized in each disease or technology area so as to encourage a sense of ownership and motivate employees to increase their productivity and efficiency.

Outline of Major Changes at Eisai Product Creation Systems (EPCS)

Unit or Organization	Function	Major Changes
PCUs and CFUs		
Oncology PCU	Product creation in oncology	Strengthening of clinical support functions
Neuroscience & General Medicine PCU	Product creation in neurology and related research areas	Increased focus on Open Innovation and dissolution of medicinal chemistry function at EMEA Knowledge Centre; strengthening of clinical support functions
Morphotek PCU	Product creation based on original antibody technologies	
KAN PCU	Product creation based on elucidation of cell functions (including antibody drugs)	
Japan/Asia Clinical Research PCU	Clinical research conducted in Japan and Asia	Added clinical support function
Pharmaceutical Science & Technology CFU	Chemistry, manufacturing and controls (CMC)	Establishment of new Biopharmaceutical Development Department; consolidation of functions for small-molecule process development to Japan and India and dissolution of related functions at Andover site
Biopharmaceutical Assessment CFU	Drug metabolism and pharmacokinetics (DMPK), safety	
Biomarkers & Personalized Medicine CFU	Biomarkers	
Next Generation Systems CFU	Chemical library, screening	
Scientific & Operational Clinical Support CFU	Clinical support (including statistical analysis and clinical pharmacology functions)	Dissolution (transfer of clinical support function to other PCUs/CFUs, placing of statistical analysis and clinical pharmacology functions under direct jurisdiction of CCLO at Product Creation Headquarters
Global Regulatory Affairs CFU	Regulatory affairs	Added clinical quality assurance (QA) function
Product Creation Headquarters		
Chief Product Creation Officer (CPCO)	Formulation of product creation structural strategies, corporate portfolio management and promotion of product creation activities	
Chief Innovation Officer (CINO)	Introduction of innovative new technologies and formulation of strategies for further improving productivity in product creation activities	
Chief Clinical Officer (CCLO)	Decision making related to protocol design for clinical studies and promotion of clinical operations	Addition of statistical analysis and clinical pharmacology functions

In addition to the above, Eisai's U.S.-based research subsidiary, H3 Biomedicine Inc., conducts discovery and development research specializing in the creation of oncology drugs in the area of personalized medicine.