

FOR IMMEDIATE RELEASE

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Eisai Co., Ltd.
EIDIA Co., Ltd.

LAUNCH OF STACIA CLEIA PIVKA-II EISAI DIAGNOSTIC KIT FOR DETECTING HEPATOCELLULAR CARCINOMA TUMOR MARKER WITH AUTOMATED IMMUNOANALYZER

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and its diagnostics subsidiary EIDIA Co., Ltd. (Headquarters: Tokyo, President: Atsushi Saito, "EIDIA") announced today that EIDIA will launch STACIA CLEIA PIVKA-II EISAI in Japan on July 21, 2015. The new diagnostic kit is specially designed to measure PIVKA-II, a tumor marker for hepatocellular carcinoma (HCC), with the automated immunoanalyzer STACIA manufactured by LSI Medience Co., Ltd. (Headquarters: Tokyo, President: Shinichi Yoshihara, "LSIM").

STACIA CLEIA PIVKA-II EISAI was developed by EIDIA based on a contract between EIDIA and LSIM, and marketing and manufacturing approval was obtained by EIDIA on June 8, 2015. The product will be manufactured by EIDIA and jointly promoted by EIDIA and Eisai, with technical support provided by LSIM.

PIVKA-II is widely used as a tumor marker in HCC diagnosis due to its high specificity to HCC. Currently, EIDIA markets four other PIVKA-II diagnostic kits in Japan: EITEST PIVKA-II for cup-type enzyme immunoassay, PICOLUMI PIVKA-II MONO for electro-chemiluminescence immunoassay, LUMIPULSE PIVKA-II EISAI for automated chemiluminescent enzyme immunoassay, and E test TOSOH II (PIVKA-II) for automated enzyme immunoassay analyzer.

With the launch of this new PIVKA-II diagnostic kit for use with LSIM's STACIA systems, Eisai and EIDIA seek to enhance the usability of tumor marker tests for diagnosis of HCC as well as treatment response assessment. Through these endeavors, the companies aim to make a greater contribution to addressing the diverse needs of patients, their families and healthcare professionals and increasing the benefits their products provide.

[Please refer to the following notes for a product outline and a product photograph.]

<Media Inquiries>

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

Public Relations Section, EIDIA Co., Ltd.
Tel: +81-(0)3-3865-4311

[Notes to editors]

■ Product Outline

Product name	STACIA CLEIA PIVKA-II EISAI
Indication for use	Quantitative measurement of abnormal prothrombin (PIVKA-II) in serum (as diagnostic aid in determining malignant tumors, etc.)
Compatible with	STACIA
Packaging	Kit for 100 tests
Recommended Price	150,000 Japanese yen
Manufacturer and Distributor	EIDIA Co., Ltd.
Marketing Co-promoter	Eisai Co., Ltd.
Technical Support	LSI Medience Co., Ltd.

■ Glossary of Terms

1. Automated Immunoanalyzer STACIA

STACIA is a fully automated immunoassay analyzer that supports six different analysis methods in a single unit, and can analyze a wide range of variables (blood/coagulation test, immunoassay inspection, biochemical testing, etc.) compared to other companies' products. By setting reagents and variables, it is possible to scan for various types of malignant tumor, heart disease and endocrine disease.

2. About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) accounts for the majority of diagnosed liver cancer cases and in Japan ranks as the fourth leading cause of death for men, and seventh for women, across all malignant tumor types (2015). Most cases of HCC develop from chronic hepatitis and/or hepatic cirrhosis associated with viral hepatitis infections.

3. About PIVKA-II

PIVKA-II, equal to and also known as des- γ -carboxyprothrombin (DCP), is an abnormal form of the protein prothrombin (coagulation factor II) and is induced by a deficiency of vitamin K. First reported to appear in the blood of patients with HCC in 1984, it is today recognized as a tumor marker for HCC and widely measured as a routine diagnostic aid.

■ Product Photograph

