

FOR IMMEDIATE RELEASE

December 13, 2013

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

LAUNCH OF MEASUREMENT REAGENT KIT “E TEST [TOSOH] II (PIVKA-II)” FOR USE WITH TOSOH AIA SYSTEMS IN DETECTING HEPATOCELLULAR CARCINOMA DIAGNOSTIC-AID MARKER PIVKA-II/DCP IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) and its diagnostics subsidiary EIDIA Co., Ltd. (Headquarters: Tokyo, President: Atsushi Saito, “EIDIA”) announced today that EIDIA will launch E test [TOSOH] II (PIVKA-II), a new measurement reagent kit, in Japan on December 17, 2013. The new test kit is specially designed for use with AIA automated immunoassay analyzers currently marketed by Tosoh Corporation (Headquarters: Tokyo, President: Kenichi Udagawa, “Tosoh”), to detect the hepatocellular carcinoma (HCC) diagnostic-aid marker PIVKA-II, also known as des- γ -carboxyprothrombin (DCP).

The new test kit was developed by Tosoh under a joint research agreement between Tosoh and EIDIA and approved for manufacture and sales in Japan on June 19, 2013. Following launch, it will be manufactured by Tosoh and distributed by EIDIA, with Eisai to cooperate with EIDIA in conducting associated promotional activities.

PIVKA-II is widely used as a tumor marker in HCC diagnosis due to its high specificity to HCC. Other PIVKA-II test kits currently marketed in Japan by EIDIA include the cap-type enzyme immunoassay EITEST[®] PIVKA-II, electro-chemiluminescence immunoassay PICOLUMI[®] PIVKA-II, and automated chemiluminescent enzyme immunoassay system LUMIPULSE[®] PIVKA-II EISAI. With the domestic launch of this new PIVKA-II measurement reagent kit for use with Tosoh’s AIA systems (AIA-2000, AIA-1800, AIA-900 and AIA-600 II), which are in wide use by healthcare professionals on the medical frontline, Eisai and EIDIA seek to enhance the utility of HCC diagnostic aids and increase the effectiveness of treatment benefit evaluations. 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,
glossary of terms, corporate outlines, and a product photograph.]**

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■ Product Outline

Product name	E test 「TOSOH」 II (PIVKA-II)
Indication for use	Quantitative measurement of abnormal prothrombin (PIVKA-II) in serum (as diagnostic aid in determining malignant tumors, etc.)
Direction for use	Testing reagent for AIA-2000, AIA-1800, AIA-900, AIA-600 II
Packaging	Kit for 100 tests
Recommended price	150,000 yen
Manufacturer	Tosoh Corporation
Distributor	EIDIA Co., Ltd.
Co-promoter	Eisai Co., Ltd.

■ Glossary of Terms

1. Automated Immunoassay Analyzer

An immunoassay analyzer that uses monoclonal antibodies to perform automated, speedy, specific and highly sensitive measurements *in vitro* of clinical indicators such as tumor markers and hormones. It is used in combination with measurement reagents to examine various types of tumors, cardiac and endocrine disorders, allergies and other diseases.

2. Hepatocellular Carcinoma (HCC)

HCC accounts for the majority of diagnosed liver cancer cases and in Japan ranks as the fourth leading cause of death across all malignant tumor types (2011). Since most cases of HCC are developed from chronic hepatitis and/or hepatic cirrhosis associated with viral hepatitis infections, frequent and detailed monitoring of the pathological process of HCC is key to early diagnosis and initiation of treatment.

3. Protein Induced by Vitamin K Absence or Antagonist II (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.

4. Tumor Marker

Any substance that leads to an increased concentration in the blood and other body fluids when a tumor develops and as such is utilized as an indicator of tumor formation.

■ Company Outlines

Eisai Co., Ltd.

Representative	Haruo Naito
Head Office	4-6-10 Koishikawa, Bunkyo-ku, Tokyo, Japan
Scope of Business	Research and development, production, sales and export of pharmaceutical products
Capital	44,985 million yen (as of March 31, 2013)

EIDIA Co., Ltd.

Representative	Atsushi Saito
Head Office	1-10-6 Iwamoto-cho, Chiyoda-ku, Tokyo, Japan
Scope of Business	Manufacturing, marketing and research and development of <i>in vitro</i> diagnostics, laboratory reagents, laboratory instruments and other supplies
Capital	5,262 million yen (as of March 31, 2013; wholly owned subsidiary of Eisai Co., Ltd.)

Tosoh Corporation

Representative	Kenichi Udagawa
Head Office	3-8-2 Shiba, Minato-ku, Tokyo, Japan
Scope of Business	Basic chemicals, petrochemicals, specialty products including <i>in vitro</i> diagnostics, bioscience products, fine chemicals
Capital	40,633 million yen (as of March 31, 2013)

■ Product Photograph

