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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. 08-35

May 22, 2008

Eisai Co., Ltd.

**NON-IONIC CONTRAST AGENTS, IOMERON[®] 350 AND IOMERON[®] 350 SYRINGE,
RECEIVE APPROVAL FOR USE IN DYNAMIC CT LIVER IMAGING**

Bracco-Eisai Co., Ltd. (Headquarters: Tokyo, President: Osamu Hirano), an associate company of Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito), announced that its non-ionic contrast agents, *Iomeron[®] 350* and *Iomeron[®] 350 syringe* (generic name: iomeprol), received additional approval for usage in dynamic computed tomography of the liver imaging (dynamic CT). In addition, a higher dose administration of *Iomeron[®] 350 syringe* (135 ml formulation) also received approval. (135 ml has not yet been added to the National Health Insurance price listing)

Tumors in the liver are generally diagnosed with a dynamic CT by utilization of a multi-slice CT which has been popular in medical instructions recently. This diagnostic method allows a rapid and clear visualization of the entire liver within the holding of one breath. However, there has been a clinical need for a high concentration contrast agent that can be administered in a relatively short period of time. In addition, medical institutions have also desired a contrast agent with a higher dosage administration to better meet specialty patient needs.

Iomeron[®] 350 and *Iomeron[®] 350 syringe* are high concentration formulations of *Iomeron[®]*. The approval announced today will allow the intravenous administration at 1.8 ml/kg, and the dosage can be adjusted depending on the patient's weight (up to 135 ml). With these new formulations, contrast agent can be rapidly administered at the time of dynamic CT imaging using the multi-slice CT and patients with a higher body mass index can receive sufficient dosage for optimum imaging. A post-marketing surveillance will be conducted for the newly approved indication and dosage as an integral component of pharmacovigilance efforts to ensure safe usage of the products.

With this new indication and new high dose formulation of *Iomeron[®]*, Eisai and Bracco-Eisai will make further contributions to the improvement of liver disease diagnosis by dynamic CT imaging using the multi-slice CT as well as to decreasing patients' burdens associated with such diagnostic procedures.

[Please refer to the following notes for terminology and the product]

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<Note to Editor>

1. About Dynamic Computed Tomography of the Liver/ Multi-Slice CT

Dynamic Computed Tomography of the Liver

Dynamic computed tomography (Dynamic CT) is an imaging method of computer tomography of areas around the liver. It evaluates the dynamics of a contrast agent by scanning portions of the liver during the arterial or portal phases after contrast agent administration at a certain timing.

Unlike other organs, blood flow in the liver is controlled by the hepatic artery and the portal vein. Hepatocellular carcinoma and other primary liver tumors are known for their hyper vascularity, thus the hepatic artery is superior than the portal vein and it is emphasized during the imaging process. However, in metastatic liver cancer, the diagnosis generally involves the imaging during the portal phase.

In order to enhance the contrast of the hepatic artery, a contrast agent must be administered by increased dosing rate or at a higher concentration. On the other hand, either an increase in the gross dose of a contrast agent or a high concentration agent is required to achieve contrast enhancement of the portal vein.

Multi-Slice CT

Unlike a CT scanner that collects one slice of data with one single rotation by one detector ring, multi-slice CT imaging can obtain data for multiple slices with one rotation by using multiple detector rings lined up with axis. It can be used for scanning adjacent or overlapping slices, which is difficult in helical CT imaging that scans by moving one detector ring. Decreased radiation and increase speed for scanning are also benefits of this scanning technology, which enable simple procedures and clear scanning images for infants and elderly or patients with severe conditions who often find difficulties for holding a breath for a long time.

2. Product Information (Additional information including Dosage and Administration)

Product Name: Iomeron® 350, Iomeron® 350 syringe

Generic Name: Iomeprol

Indication (No change):

Cerebral angiography, thoracic angiography, Abdominal angiography, Peripheral angiography, intravenous digital subtraction angiography, intraarterial digital subtraction, Visualization in computed tomography and intravenous urography

Dosage and administration:

Dynamic computed tomography: 40 to 100 ml

In the case of dynamic computed tomography of the liver, 1.8 ml/kg can be administered by intravenous injection depending on weight (up to 135 ml)

Volume (Underline is an additional one this time)

Iomeron® 350	20 ml
Iomeron® 350	50ml
Iomeron® 350	100ml
Iomeron® 350 syringe	50ml
Iomeron® 350 syringe	75ml
Iomeron® 350 syringe	100ml
<u>Iomeron® 350 syringe</u>	<u>135ml (drug price has not been listed yet)</u>

Features

Iomeron® is a nonionic contrast agent which was developed by Bracco S.p.A. in Italy. In comparison with similar density contrast media, Iomeron® has distinguishing features such as low osmolarity and low viscosity, and Iomeron® is an effective contrast media for several types of angiography, visualization in computed tomography and intravenous urography. In Japan, the vial formulation was launched in May

1994, and the syringe formulation was added in June 1996. The manufacturer is Bracco-Eisai Co., Ltd. and distribution/sales are by Eisai Co., Ltd. As of June 2007, Iomeron® has been approved and marketed in 42 countries including Japan.

Manufacturer and Distributor

Manufacturer: Bracco-Eisai Co., Ltd.
Distribution/Sales: Eisai Co., Ltd.

Nonionic contrast media Iomeron® product series ([] indicates volume and Underline is an additional one this time)

Iomeron® 300 (For urinary tract, CT and angio) [20 ml, 50 ml and 100 ml]
Iomeron® 350 (For urinary tract, CT and angio) [20 ml, 50 ml and 100 ml]
Iomeron® 400 (For urinary tract, and angio) [20 ml, 50 ml and 100 ml]
Iomeron® 300 syringe (For urinary tract, CT and angio) [50 ml, 75 ml and 100 ml]
Iomeron® 350 syringe (For urinary tract, CT and angio) [50 ml, 75 ml, 100 ml and 135 ml (drug price has not been listed yet)]

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