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Eisai Co., Ltd.

EISAI SUBMITS MARKETING AUTHORIZATION APPLICATION IN JAPAN FOR EMBOLIC BEAD E7040

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has submitted a marketing authorization application in Japan seeking approval to market the embolic bead E7040 for Transcatheter Arterial Embolization (TAE) in patients with hepatocellular carcinoma(HCC).

E7040 is a hydrophilic microspherical particle produced from a polyvinyl alcohol polymer. It is an embolic bead that is injected through a catheter to physically and selectively embolize targeted blood vessels. Due to it being microscopic and uniformly spherical, the bead allows for precise embolization of targeted vessels based on vascular diameter and tumor size. The Japanese Ministry of Health, Labour and Welfare's "Study Council for the Early Introduction of Highly Needed Medical Devices" recommended that the product be made available on the Japanese market as early as possible at a meeting convened in January 2009.

E7040 was developed by Biocompatibles International plc (Headquarters: Farnham, United Kingdom, CEO: Crispin Simon, "Biocompatibles") and is currently marketed in more than 40 countries worldwide, mainly in Europe and the United States, as an effective embolization material intended for the purpose of embolizing HCC and a variety of other malignant hypervascularized tumors (brand name in Europe: DC Bead®, brand name in the U.S.: LC Bead™). Eisai acquired the exclusive rights to develop and market the product in Japan in a licensing agreement it concluded with Biocompatibles in July 2009.

The total annual number of HCC patients in Japan is estimated at 67,000, with about 40,000 new cases being diagnosed each year. TAE, one of the treatment options available for HCC, uses an embolization material to selectively embolize the artery that supplies the tumor with nutrients, thereby selectively inducing tumor necrosis. This kind of therapy is performed on around half of all HCC patients, with an estimated 20,000 patients qualifying for the procedure each year.

Eisai positions oncology as a therapeutic area of focus. Having already demonstrated its commitment to the field with TREAKISYM® Injection 100 mg (manufactured and co-marketed by: SymBio Pharmaceuticals Limited), the first anticancer agent for the company to launch in Japan, and eribulin mesylate (generic name, brand name in the U.S.: Halaven™), an in-house developed novel anticancer agent for which regulatory applications were simultaneously submitted to the health authorities in Japan, the United States and European Union (approved in the U.S., under regulatory review in Japan), Eisai will continue to make every effort to ensure the early introduction of E7040 onto the Japanese market. Eisai will also continue to enhance its portfolio of oncology-related products in Japan, and make further contributions to addressing the diversified needs of cancer patients and their families.

[Please refer to the following notes for further information on E7040 and Transcatheter Arterial Embolization]

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[Notes to editors]

1. About E7040

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2. Transcatheter Arterial Embolization （TAE）

Transcatheter Arterial Embolization (TAE) is a kind of therapy used to selectively induce tumor necrosis in HCC by injecting an embolization material into the hepatic artery that supplies the tumor so as to occlude the nutrient artery. There are two types of TAE, one that involves embolization without chemotherapy, and Transcatheter Arterial Chemoembolization (TACE), which is performed in combination with chemotherapeutic agents to induce tumor necrosis and adjunctively suppress cancer cell activity.

3. Malignant Hypervascularized Tumor

A malignant hypervascularized tumor most commonly refers to hepatocellular carcinoma, renal cell carcinoma cancer, bone and soft tissue sarcoma, and other malignant tumors that receive nourishment via a sophisticated vascular network formed in tumor tissue.