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Eisai Co., Ltd.

EISAI RECEIVES MANUFACTURING AND MARKETING AUTHORIZATION FOR VASCULAR EMBOLIZATION DEVICE DC BEAD® IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has received manufacturing and marketing authorization in Japan from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the DC Bead®, a vascular embolization device (specially controlled medical device), approving the device for transcatheter arterial embolization (TAE) therapy in patients with hepatocellular carcinoma (HCC).

The DC Bead is a hydrophilic microspherical particle produced from a cross-linked polyvinyl alcohol polymer. It is an embolic bead that is injected through a catheter to selectively embolize targeted blood vessels. TAE, one of the treatment options available for HCC, is performed by injecting an embolization material into the hepatic artery, which is the artery that supplies the tumor with nutrient blood, to achieve selective embolization and thereby induce tumor necrosis.

The device was developed by Biocompatibles, a BTG International group company, and is currently available in more than 40 countries worldwide, including Europe and the United States, as an effective embolization material for treating HCC and other hypervascularized tumors. Following a recommendation by the MHLW's Study Council for the Early Introduction of Highly Needed Medical Devices that the device be made available in Japan as early as possible, Eisai acquired the exclusive rights to develop and market the product in Japan from Biocompatibles in July 2009 and submitted its manufacturing and marketing authorization application to the MHLW in December 2010.

In Japan, Eisai already markets HCC-related imaging diagnostics, namely, nonionic contrast medium Iomeron®, nonionic contrast medium for MRI ProHance®, in-vitro diagnostic PIVKA-II Kit (which measures HCC tumor marker PIVKA-II), and liver disease medication and anti-allergy agent Stronger Neo-Minophagen® C. By obtaining marketing authorization for the DC Bead in Japan, Eisai seeks to further enhance its portfolio of HCC-related products in the country and continue to contribute to addressing the diverse needs of, and increasing the benefits provided to, patients with HCC and their families.

[Please refer to the following notes for an outline of the DC Bead and further information on TAE and hypervascularized tumors.]

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[Notes to editors]

1. DC Bead® Outline

The DC Bead is a hydrophilic microspherical particle produced from a cross-linked polyvinyl alcohol polymer. It is an embolic bead that is injected through a catheter to selectively embolize targeted blood vessels. As the device is microscopic and uniformly spherical, it allows for sustained embolization of targeted vessels based on vascular diameter and tumor size. The embolization material contained in the device has been confirmed by endoscopic observation to cause blood clotting in targeted blood vessels. Following its regulatory approval in Japan, the product will made available in three particle sizes (100-300 µm, 300-500 µm, and 500-700 µm) so that a suitable particle size can be selected based on vascular diameter, tumor size and the extent of intended embolization in the targeted blood vessel.

In addition to the DC Bead's currently approved indication in Japan for transcatheter arterial embolization (TAE) therapy in patients with hepatocellular carcinoma (HCC), Eisai is currently also carrying out Phase III clinical trials of the device as an effective embolization material for treating other hypervascularized tumors in Japan.

2. About Transcatheter Arterial Embolization (TAE)

TAE is a therapy that selectively obstructs blood circulation to induce necrosis in hepatocellular carcinoma (HCC) by injecting embolization material into the hepatic artery, the artery that supplies nutrient blood to the tumor. In contrast to healthy liver cells, which receive blood from both the hepatic artery and portal vein, HCC cells mainly receive blood from the hepatic artery via a vascular network formed in the tumor tissue. Consequently, by using embolizing material to selectively embolize blood vessels in the hepatic artery, selective necrosis can be effectively induced in the tumor. There are two types of TAE therapy: one involving embolization without chemotherapy, and transcatheter arterial chemoembolization (TACE), the latter of which is performed in combination with chemotherapeutic agents to induce the tumor necrosis and adjunctively suppress cancer cell activity.

3. About Hypervascularized Tumors

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