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Eisai Co., Ltd.

EISAI RECEIVES ADDITIONAL APPROVAL IN JAPAN FOR VASCULAR EMBOLIZATION DEVICE DC BEAD® AS TREATMENT OF HYPERVASCULAR TUMORS AND ARTERIOVENOUS MALFORMATIONS

To be Applicable for Insurance Reimbursement Once Listing Procedures are Completed

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has received additional approval for the vascular embolization device DC Bead® (specially controlled medical device, "DC Bead") to be used for the treatment of hypervascular tumors and arteriovenous malformations (AVM) in Japan. The product will be able to be reimbursed for this newly approved purpose once procedures are completed for insurance reimbursement listing as a specially controlled medical device (the original purpose for treatment of hepatocellular carcinoma is already eligible for reimbursement).

DC Bead contains hydrophilic microspheres made from cross-linked polyvinyl alcohol polymer. Developed by Biocompatibles UK Limited (Biocompatibles), a BTG International group company, as an intravascular embolization device, it is injected via catheter into targeted blood vessels to achieve selective embolization. Eisai acquired the exclusive rights to develop and market DC Bead in Japan from Biocompatibles in July 2009 and received manufacturing and marketing approval for the device from Japan's Ministry of Health, Labour and Welfare (MHLW) in April 2013 for use in transcatheter arterial embolization in hepatocellular carcinomas. Eisai subsequently launched DC Bead in Japan in February 2014.

A hypervascular tumor most commonly refers to hepatocellular carcinoma, certain metastatic liver cancers, renal cell carcinoma, soft tissue sarcoma, uterine fibroids and other tumors that are nourished via a sophisticated vascular network developed in tumor tissue. An AVM is a congenital vascular malformation that leads to various functional, organic and developmental disorders that are caused by an abnormal connection between the arteries and veins disrupting the normal circulation of blood. By selectively embolizing the sections of blood vessels that are supplying nutrients to tumor tissue and malformations, it is possible to necrose or reduce tumors, and improve associated symptoms.

It was recommended at the MHLW's Study Council for the Early Introduction of Highly Needed Medical Devices that DC Bead be made available as soon as possible as a device indicated for the treatment of hypervascular tumors as well as AVM. Upon receiving this recommendation, Eisai conducted clinical studies aiming to confirm safety and efficacy of using DC Bead as an embolization material on hypervascular tumors and AVM (excluding central nervous system, heart and lung AVM) in Japan in order to secure an indication expansion. Results of these studies suggested safety and efficacy for DC Bead as replenishment material to promote embolization within the arteries of the central circulatory system, which led Eisai to submit an application for an additional purpose in September 2014.

Through the approval of this indication expansion for DC Bead, Eisai seeks to further contribute to addressing the diverse needs of, and increasing the benefits provided to, patients and their families as well as healthcare providers.

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[Notes to editors]

1. About DC Bead

DC Bead contains hydrophilic microspheres (beads) made from cross-linked polyvinyl alcohol polymer. As a vascular embolization device, it is injected via catheter into targeted blood vessels to achieve selective embolization. Due to the beads being both microscopic and uniformly spherical, DC Bead allows for sustained embolization of targeted blood vessels based on vascular diameter and tumor size, with each embolization procedure confirmed through endoscopic observation of the targeted vessels. The device is available within Japan in three bead sizes (100-300 μm, 300-500 μm, and 500-700 μm) so that an appropriate bead size can be selected based on vascular diameter, tumor size and extent of intended embolization in the targeted blood vessel. Primary adverse effects observed in clinical trials conducted in Japan include post-embolization symptoms, lymphopenia and constipation. In April 2013, DC Bead received marketing approval for transcatheter arterial embolization therapy in hepatocellular carcinoma and was launched in Japan in February 2014.

2. About Hypervascular Tumors

A hypervascular tumor most commonly refers to hepatocellular carcinoma, certain metastatic liver cancers, renal cell carcinoma, soft tissue sarcoma, uterine fibroids and other tumors that are nourished via a sophisticated vascular network developed in tumor tissue. By selectively embolizing blood vessels to cut off the nutrient supply to the tumor tissue of these types of hypervascular tumors, it is possible to necrose or reduce them.

3. About Arteriovenous Malformations (AVM)

An AVM is a congenital vascular malformation that leads to various functional, organic and developmental disorders brought about by an abnormal connection between the arteries and veins disrupting the normal circulation of blood. Although the standard treatment consists of surgical resection of the malformation, in many cases it is difficult to completely remove the malformation while preserving the function and outward appearance of the remaining part, which often results in relapse. Vascular embolization therapy attempts to improve these symptoms by blocking off abnormal blood flow through the malformation, which returns blood circulation to normal and also restores blood flow in the surrounding healthy veins.