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Eisai Co., Ltd.

EISAI SUBMITS APPLICATION IN JAPAN FOR INDICATION EXPANSION OF VASCULAR EMBOLIZATION DEVICE DC BEAD® TO INCLUDE TREATMENT OF HYPERVASCULARIZED TUMORS AND ARTERIOVENOUS MALFORMATIONS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has submitted an application for the indication expansion of the vascular embolization device DC Bead® (specially controlled medical device, "DC Bead") for additional use in the treatment of hypervascularized tumors and arteriovenous malformations (AVM) in Japan.

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 authorization 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 launched DC Bead with this indication in Japan in February 2014.

A hypervascularized tumor most commonly refers to hepatocellular carcinoma, certain metastatic liver cancers, renal cell carcinoma, soft -tissue osteosarcoma, 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 hypervascularized tumors, it is possible to kill or reduce them. 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 hypervascularized tumors as well as AVM (excluding central, heart and lung AVM), therefore Eisai conducted clinical studies on hypervascularized tumors and AVM accordingly in Japan. Results of these studies suggested that DC Bead was highly efficient as a medical device, which has led to this application for indication expansion.

Eisai positions oncology as a key franchise area. In Japan, the company currently markets the anti-cancer products of Halaven®, TREAKISYM® Injection 100mg as well as Gliadel® 7.7 mg Implant, and in June 2014, submitted a marketing authorization application for lenvatinib mesylate for the treatment of thyroid cancer. Through this indication expansion application for DC Bead, Eisai seeks to further contribute to addressing the diverse needs of, and increasing the benefits provided to, patients with cancer 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 2013, DC Bead received marketing approval for transcatheter arterial embolization therapy in hepatocellular carcinoma and was launched in Japan in February 2014.

2. About Arteriovenous Malformations (AVM)

An AVM is a congenital vascular malformation brought about by various functional, organic and developmental disorders that occur when there is 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 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.