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Eisai Co., Ltd.

NOTICE REGARDING PARTIAL LABEL CHANGE FOR VASCULAR EMBOLIZATION DEVICE DC BEAD®

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has received approval for a partial label change for the vascular embolization device DC Bead® (specially controlled medical device) in Japan. The product is to be used for transcatheter arterial embolization in patients with hypervascular tumors (excluding uterine fibroids).

In real-world clinical settings, it was found that DC Bead was not being used in the treatment of uterine fibroids and arteriovenous malformations. Following confirmation at related academic associations and subsequent consultation with the regulatory authority, an application for a partial label change for the relevant indication was submitted, upon which this approval is based.

With the partial label change for DC Bead, Eisai is striving to ensure that accurate information is provided to healthcare professionals.

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[Notes to editors]

1. Changes to the DC Bead Label

Underlined parts have been revised, strikethrough parts have been deleted.

Revised Label	Label Prior to Revision
【Purpose of use】 Transcatheter arterial embolization in patients with hypervascular tumors <u>(excluding uterine fibroids)</u>	【Purpose of use】 Transcatheter arterial embolization in patients with hypervascular tumors ~~and arteriovenous malformations~~