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Eisai Co., Ltd.

PROMOTION AND DISTRIBUTION AGREEMENT WITH MYLAN INDIA FOR ERIBULIN SECOND BRAND IN INDIA

AIMING TO EXPAND AVAILABILITY OF ERIBULIN TO PATIENTS IN INDIA WITH TWO BRANDS HALAVEN® AND TECERIS®

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that Eisai's subsidiary Eisai Pharmaceuticals India Pvt. Ltd. (Location: Andhra Pradesh, "Eisai India") and Mylan N. V. (Headquarters: Pennsylvania, United States) subsidiary Mylan India have entered into a license agreement to promote and distribute the second brand TECERIS® for the anticancer agent eribulin mesylate (eribulin) in India.

Under this agreement, eribulin will be supplied to Mylan India by Eisai India as well as promoted and distributed by Mylan India as TECERIS. Mylan India has a wide portfolio of medicines in oncology and brand building ability in India. Eisai group positions this agreement as an important strategy for expanding access to eribulin following the tiered-pricing model* in which the cost burden to patients is differentiated according to income level. Further availability of eribulin to patients all over India is expected by supplying eribulin in two brands, two channels: Halaven® by Eisai India and TECERIS by Mylan India.

Eribulin is a novel anticancer agent discovered in-house by Eisai. In India, Eisai is steadily expanding the availability of eribulin to patients since Eisai India has launched eribulin as Halaven and introduced a tiered-pricing model in October 2013. Eribulin's indication for breast cancer in India is the locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.

The number of women diagnosed with breast cancer in India has increased in recent years, with an estimated 163,000 new cases of breast cancer and approximately 87,000 related deaths in 2018.[1] Breast cancer is now the most frequently diagnosed cancer in Indian women.[1]

Eisai group positions oncology as a key therapeutic area, and is aiming to discover revolutionary new medicines with the potential to cure cancer. In addition, Eisai group will continue to adopt proactive measures aimed at increasing access to its innovative pharmaceutical products in emerging countries and the developing world in order to contribute to an increase in the benefits provided to local patients and their families.

* Tiered-Pricing sets the multiple cost burden to patients from full payment by the patient to free of charge in accordance with their income levels. In India, approximate 30% of patients, who have treated with Halaven, used the support program by Tiered-Pricing, and it is assumed that the patients' access to eribulin was improved by approximate 45% with the program.

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[Notes to editors]

1. About eribulin mesylate (product name: Halaven, “eribulin”)

Eribulin is in the halicondrin class of microtubule dynamics inhibitors with a novel mechanism of action. Structurally, eribulin is a simplified and synthetically produced version of halichondrin B, a natural product isolated from the marine sponge *halichondria okadai*. Eribulin is believed to work by inhibiting the growth phase of microtubule dynamics which prevents cell division. In addition, non-clinical studies showed eribulin’s unique actions in the tumor microenvironment such as an increase in vascular perfusion and permeability in tumor cores,[2] promotion of the epithelial state, decrease in capacity of breast cancer cells to migrate,[3] and etc.

Eribulin was first approved as a treatment in the United States in November 2010 for patients with metastatic breast cancer. Eribulin is currently approved for use in the treatment of breast cancer in over 70 countries worldwide, including Japan and countries in Europe, the Americas and Asia. Furthermore, eribulin was first approved as a treatment for soft tissue sarcoma in the United States in January 2016, and is approved in over 60 countries including Japan and in Europe and Asia. Furthermore, eribulin has been designated as an orphan drug for soft tissue sarcoma in the United States and Japan.

Specifically, eribulin is approved for the following indications in India.
Locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.
Unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease.

2. About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com.

[1] International Agency for Research on Cancer（http://globocan.iarc.fr/）
[2] Funahashi Y et al., Eribulin mesylate reduces tumor microenvironment abnormality by vascular remodeling in preclinical human breast cancer models. *Cancer Sci*., 2014; 105, 1334-1342
[3] Yoshida T et al., Eribulin mesilate suppresses experimental metastasis of breast cancer cells by reversing phenotype from epithelial-mesenchymal transition (EMT) to mesenchymal-epithelial transition (MET) states. *Br J Cancer*, 2014; 110, 1497-1505