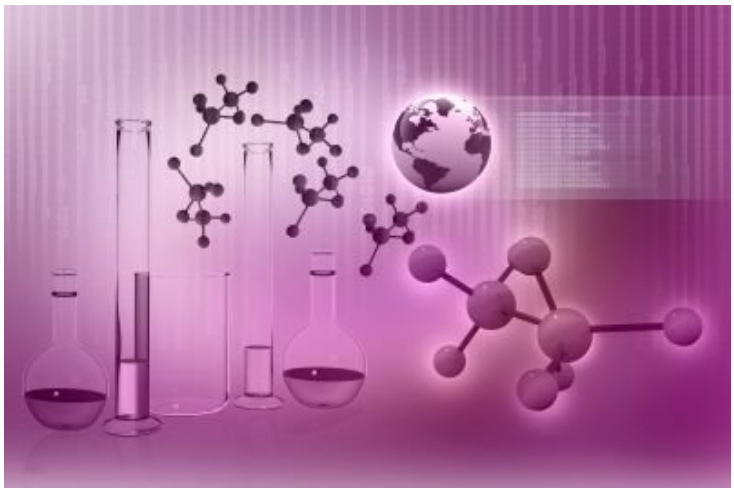
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Japanese pharmaceutical major Eisai Co. Ltd. has submitted applications to regulatory authorities in Japan, United States and Europe (MHLW, FDA and EMA respectively) seeking an additional indication for its in-house developed anticancer agent Halaven (eribulin mesylate) as a treatment for soft tissue sarcoma.

Eisai claims that Halaven is the first and only single agent systemic therapy to demonstrate an improvement in overall survival (OS) in people previously treated for soft tissue sarcomas in a randomized controlled trial to date.

In a Phase III clinical study (Study 309) which examined the efficacy and safety of Halaven versus dacarbazine in patients with locally advanced or recurrent and metastatic soft tissue sarcoma who had disease progression following standard therapies, Halaven is said to have demonstrated a statistically significant extension in the study's primary endpoint of OS over the comparator treatment dacarbazine.

Soft tissue sarcoma is a collective term for a diverse group of malignant tumors that occur throughout the soft tissue (fat, muscle, nerves, fibrous tissues and blood vessels) in the body.

Approximately 12,000 patients in the United States and 29,000 patients in Europe are diagnosed with soft tissue sarcoma each year. According to a patient survey conducted by the MHLW, there are approximately 4,000 patients with soft tissue sarcoma in Japan. Meanwhile, Halaven has been designated as an orphan drug for the treatment of soft tissue sarcoma in the United States and Japan.

Halaven is a halichondrin class microtubule dynamics inhibitor with a novel mechanism of action. It was first approved for the treatment of metastatic breast cancer in the United States in November 2010, and is currently approved in approximately 60 countries including Japan and countries in Europe, the Americas and Asia.