The positive opinion received from the CHMP is a recommendation to expand the indication to include patients with 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.

Eisai remains committed to providing further clinical evidence for eribulin aimed at maximizing value of the drug as it seeks to contribute further to addressing the diverse needs of, and increasing the benefits provided to, patients with cancer, their families, and healthcare providers.

[Please refer to the following notes for further information on Halaven, the pooled analysis, Study 305, Study 301 and HER2.]

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[Notes to editors]

3. About Study 305 (EMBRACE)

In the Phase III clinical study (Study 305, EMBRACE) of Halaven versus treatment of physician's choice (TPC) in 762 patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane,