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Eisai Co., Ltd.

EISAI PRESENTS NEW QUALITY OF LIFE FINDINGS IN PATIENTS WITH

®

(eribulin mesylate, "eribulin") improved overall quality of life (QOL) (Global Health Status and QOL, "GHS/QOL") significantly more than capecitabine over the course of a Phase III study (Study 301) in patients with mae c15(v)TL 9a5512 TL 81.3v1oth dy 8I5Q6sg102 Ti31 TwT(icore than)]09tt.(o bi)(the oiun0n.0y S)0C

on an analysis of responses to questions on QOL related to the well-being of those patients who participated as subjects in Study 301. indicate overall patient QOL, were shown to improve significantly ulin versus capecitabine (p=0.048) over the course of treatment. y better than capecitabine in assessments of cognitive functioning 043), and diarrhea (p=0.001). In comparison, capecitabine red to eribulin in evaluations of emotional functioning (p=0.033), set by hair loss (p=0.023).

ajor impact on patient QOL such as difficulties with family life and ility at work, and participation in common social activities. A central patients with metastatic breast cancer is to extend life for as long as patient QOL is maintained. Effective QOL management is also eatment to continue, thus enabling the maximum benefits of the

serve to offer better understanding on how the QOL of patients with either treatment, and Eisai believes that the findings will serve as a med decisions when considering which treatment to undergo. The ding further clinical evidence for eribulin aimed at maximizing value urther to addressing the diverse needs of, and increasing the benefits families, and healthcare providers.

[Please refer to the following notes for further information on the Study 301 QOL assessments, the assessment scales used, and Halaven.]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. About the Study 301 QOL Assessments

Study 301 was an open-label, randomized, two-parallel-arm, multicenter study designed to evaluate Halaven versus capecitabine in 1,102 women with locally advanced or metastatic breast cancer who had up to three prior chemotherapy regimens in the (neo)adjuvant setting, and no more than two prior regimens for locally advanced and/or metastatic disease. The regimens must have included an anthracycline and a taxane. Although eribulin did not achieve a statistically significant result when compared to capecitabine in terms of overall survival (OS) and progression-free survival (PFS), the co-primary endpoints of the study, eribulin did demonstrate a trend favoring improved OS (eribulin median OS: 15.9 months, capecitabine median OS: 14.5 months; HR 0.879; 95% CI: 0.770-1.003; p=0.056). Additionally, a later PFS assessment carried out by an independent evaluation body concluded that there was no significant difference between the two drugs (eribulin median PFS: 4.1 months, capecitabine median PFS: 4.2 months, HR 1.079; 95% CI: 0.932-1.250; p=0.305).

Study 301 had a secondary endpoint of quality of life (QOL) assessed using the EORTC QLQ-C30 and QLQ-BR23 questionnaires at baseline, 6 weeks, and