**INTRODUCTION**

Eribulin mesylate is a synthetic analog of halichondrin B, a natural product isolated from the marine sponge Halichondria okadae.1,2 It is a mitotic inhibitor that inhibits microtubule dynamics, leading to depolymerization of microtubules and arrest of mitosis.3-5 Eribulin mesylate was approved in the US, EU, Japan, and other countries based on the E3595 study, a phase 2, multicenter, single-arm study of eribulin mesylate + trastuzumab in women with locally advanced or metastatic HER2-positive breast cancer.6,7 The study demonstrated a survival benefit relative to the Metastatic Breast Cancer Study Assessing Physician’s Choice Versus E7389 (EMBRACE),8 which compared docetaxel to vinorelbine in women with recurrent or metastatic HER2-positive breast cancer.9

**METHODS**

**Study Design**

A summary of percent changes in the total sum of target lesion diameters is shown in Figure 3. The median number of cycles received per patient was 10.0 (range, 0-38) for eribulin + trastuzumab. A summary of patient characteristics is shown in Table 1. Patients received 5 cycles of eribulin mesylate 1.4 mg/m² infused over 2 to 5 minutes on Days 1 and 8 of each 21-day cycle and trastuzumab 2.5 mg/kg infused over 30 minutes on Days 1 of each 21-day cycle. Study treatment duration was limited to 270 days. The median duration of response (DOR) for patients whose best overall response was complete response (CR) or partial response (PR), and median progression-free survival (PFS) was 11.6 months (95% CI, 9.1-13.9) as shown in Table 2.

**RESULTS**

The 1-year PFS rate was 73.8% (95% CI, 60.9-84.3), and the ORR was 72.3% (95% CI, 60.9-84.3), and the 5-year PFS rate was 64.3% (95% CI, 51.3-77.1). The 1-year PFS rate was 78.5% (95% CI, 68.4-88.0), and the ORR was 78.5% (95% CI, 68.4-88.0), and the 5-year PFS rate was 61.4% (95% CI, 48.4-74.5). The 1-year PFS rate was 75.0% (95% CI, 64.5-85.6), and the ORR was 75.0% (95% CI, 64.5-85.6), and the 5-year PFS rate was 62.5% (95% CI, 51.3-74.4). The 1-year PFS rate was 76.6% (95% CI, 66.2-87.0), and the ORR was 76.6% (95% CI, 66.2-87.0), and the 5-year PFS rate was 64.9% (95% CI, 53.6-76.3).

**DISCUSSION AND CONCLUSIONS**

The combination of eribulin + trastuzumab as first-line therapy for patients with locally advanced or metastatic HER2-positive breast cancer was well tolerated.12,13 Eribulin + trastuzumab demonstrated clinical activity with promising safety outcomes in this heavily pretreated population and was associated with a survival benefit relative to EMBRACE, a phase 3 trial comparing docetaxel to vinorelbine in women with recurrent or metastatic HER2-positive breast cancer.10,11

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