ABSTRACT

The main inclusion and exclusion criteria were:

- Patients with MBC that have not received prior chemotherapy for advanced or metastatic disease;
- Previous chemotherapy for early stages (≤BI) including taxanes (paclitaxel and/or docetaxel) for at least 4 cycles;
- Less than a span of 16 months between the last cycle of a taxane-based regimen in the adjuvant setting and disease relapse;
- Evaluable disease based on RECIST criteria;
- Absence of HER2 over-expression (IHC of 0 or negative FISH/CISH);
- Absence of neurotoxicity > G1 48 months prior to study entry.

METHODS

Trial design

This is a phase II, multicentric, open-label, single-臂 clinical trial in patients with HER2- MBC. The study regimen consists of the administration of 1.33 mg/m² eribulin equivalent to 1.4 mg/m² eribulin mesylate as a single agent on days 1 and 8 of each 21 day cycle, until disease progression, unacceptable toxicity, or investigator’s decision (see figure 2, tables 1 and 2). The study was approved by the competent authorities and Ethics Committees from 14 participating sites in Spain and Portugal.

ELIGIBILITY CRITERIA

- Primary endpoint: time to progression (TTP).
- Secondary endpoints: toxicity, treatment response rate, progression-free survival and overall survival.

Patient selection (MBC HER2-)

Since the study start on July 2013, the enrollment has grown steadily (see graph 1) and it is expected to finalize by the end of January 2015. Currently, 30% of the 43 patients are still in the trial. Two of the patients (5%) have exceeded 12 months of treatment and as of today continue to receive the study regimen, while 25% have not yet completed the 12-month follow-up period (see graph 2).

CURRENT ENROLLMENT

Table 1. Summary of dose delays at study initiation

<table>
<thead>
<tr>
<th>Treatment Dose</th>
<th>Percentage Delay</th>
<th>Reasons for Delay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced dose</td>
<td>30%</td>
<td>Toxicity</td>
</tr>
</tbody>
</table>

ACKNOWLEDGMENTS

Acknowledgments: This presentation is the intellectual property of Velas. Contact us at clinical.communications@velas.com for permission to reprint and/or utilize.

ClinicalStudy Identifier: NCT02061085