ABSTRACT

- Endocrine therapy (ET) with aromatase inhibitors (AIs) is the standard of care for post-menopausal women with hormone receptor-positive (HR+) breast cancer (BC).
- Unfortunately, disease progression is observed in women with HR+ advanced BC while they are on ET.
- Cross-talk between the ER signaling and phosphatidylinositol 3-kinase (PI3K)-protein kinase B (AKT) signaling pathways has an important role in the clinical sensitivity of BC to ET.

METHODS

Study Design

- Multicenter, open-label, randomized, three-arm, phase 2 clinical trial (ClinicalTrials.gov identifier: NCT 01783444).
- A total of 302 post-menopausal women with HR+/HER2- ABC that has recurred or progressed on/or after prior LET or ARA, are to be enrolled.
- Patients will be randomized to receive the combination of EVE (10 mg/d), EXE (25 mg/kg/d) or EVE monotherapy (EVE: 10 mg/kg/d) twice daily for 14 days of a 28-day cycle, alternating with 14 days without drug therapy.

Table 2. Clinical Outcomes in 2 Phases of trial of Exemestane (EVE) and Capecitabine (Capecitabine) in Breast Cancer: BOLERO-6

<table>
<thead>
<tr>
<th>Phase</th>
<th>Study Design</th>
<th>Treatment</th>
<th>Key Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>Randomized, controlled phase 2 trial</td>
<td>EVE + Capecitabine vs. EVE alone</td>
<td>- OS (EVE + Capecitabine vs. EVE alone) - PFS (EVE + Capecitabine vs. EVE alone) -Change in QoL score using the EORTC QLQ-C30 questionnaire along with the BR23 module</td>
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<tr>
<td>Phase 2</td>
<td>Randomized, controlled phase 2 trial</td>
<td>Capecitabine monotherapy vs. Capecitabine monotherapy</td>
<td>- OS (Capecitabine vs. Capecitabine) - PFS (Capecitabine vs. Capecitabine)</td>
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</tbody>
</table>

Summary

- The data from this study will provide insight into the safety and efficacy of the combination of EVE and Capecitabine (1250 mg/m2 twice daily for 14 days, ET) progress. ABC progression on or after prior LE or ARA.

REFERENCES