Human Epidermal Growth Factor Receptor 2-Negative, Advanced and/or Metastatic Breast Cancer

Patient Population

- **Patients** were eligible if they had HER2− advanced or metastatic breast cancer.
- **Exclusion criteria** included treatment with CDK4/6 inhibitors within 28 days and endocrine therapy within 14 days of initiating palazestrant.
- **Patient disposition** is shown in Table 2.

Patient Disposition

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Patient disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palazestrant monotherapy</td>
<td><strong>Total</strong> (n=10)</td>
</tr>
<tr>
<td>30 mg</td>
<td>1</td>
</tr>
<tr>
<td>60 mg</td>
<td>3</td>
</tr>
<tr>
<td>120 mg</td>
<td>6</td>
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</tbody>
</table>

**Results**

- **Safety and tolerability:** The majority of treatment-emergent adverse events (TEAEs) were grade 1 or grade 2.
- **Clinical activity:** The combination of palazestrant and ribociclib demonstrated objective responses in patients with HER2− advanced or metastatic breast cancer.

Pharmacokinetics

- **Ribociclib:** Metabolized mainly by CYP3A4. Palazestrant is not a CYP3A4 inhibitor or inducer.
- **Interaction:** Ribociclib 600 mg exposure is not affected by palazestrant doses ranging from 30 to 120 mg.

Duration of Treatment

- The median duration of treatment was 24 weeks.
- **Progression-free survival (PFS):**
  - **30 mg:** 12 weeks (95% CI: 3–21 weeks)
  - **60 mg:** 18 weeks (95% CI: 10–26 weeks)
  - **120 mg:** 18 weeks (95% CI: 10–26 weeks)

Conclusions

- The combination of palazestrant at 30-120 mg with ribociclib 600 mg was well-tolerated and resulted in clinical activity and improvement of quality of life.
- **Further studies:** Additional studies are needed to confirm the clinical benefit and to explore the role of palazestrant in combination with other targeted therapies.

References


Supporting Information

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