New Targeted Therapy Slows Growth of Advanced Breast Cancer

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ASCO Perspective
"We now know that it’s possible to target this common breast cancer mutation, and it’s heartening to see that a new therapy can provide some benefits to women with advanced breast cancer. However, because the treatment has side effects, doctors will have to weigh its benefits and risks with their patients," said ASCO Expert Harold Burstein, MD, PhD, FASCO.

CHICAGO – In a phase III clinical trial, a new targeted medicine, taselisib, combined with standard hormone therapy fulvestrant (Faslodex®), halted the growth of advanced breast cancer growth by 2 months longer than hormone therapy alone, and decreased the chance of cancer worsening by 30%. Taselisib targets a common genetic abnormality in breast cancer -PIK3CA gene mutation – and is the first and most potent treatment in a relatively new class of PI3K inhibitors, according to the authors.

The study will be featured in a press briefing today and presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.
“About 40% of all patients with advanced breast cancer estrogen receptor positive have PIK3CA mutations, which means they could benefit from taselisib,” said lead study author José Baselga, MD, PhD, FASCO, the Physician-in-Chief at Memorial Sloan Kettering Cancer Center in New York. “Our findings are proof that that targeting this pathway in breast cancer is effective. However, the benefit to patients was more modest than we had hoped for, and there is a risk of considerable side effects with the addition of taselisib.”

**About Taselisib**

Taselisib is the first medicine that specifically blocks the type of PI3K protein (PI3Kalpha) that is mutated in estrogen receptor-positive breast cancers. Taselisib has also shown promising clinical benefit in early trials of patients with head and neck and certain gynecologic cancers.

**About the Study**

The SANDPIPER trial is the first and largest phase III clinical trial of taselisib, according to the authors. The trial enrolled 516 postmenopausal women with locally advanced or metastatic ER-positive, HER2-negative metastatic breast cancer that worsened or recurred despite initial hormone treatment with aromatase inhibitors. Women were randomly assigned to receive fulvestrant and placebo (176 women) or fulvestrant and taselisib (340 women).

**Key Findings**

Women who received taselisib and fulvestrant had a 30% lower chance of cancer worsening than those who received fulvestrant and a placebo, and taselisib extended the time until the cancer worsened by a median of two months (7.4 months with taselisib and fulvestrant vs. 5.4 monhts with fulvestrant and placebo). The response rate to treatment (tumor shrinkage) was more than doubled when taselisib was added (28% vs. 11.9%). Overall survival data are not yet available.

The most common severe side effects for patients who received taselisib were diarrhea, high blood sugar, and colon inflammation (colitis). Due to side effects, 17% of women who received taselisib stopped treatment early, compared to only 2% of those who did not receive the targeted therapy.

**Next Steps**

When they looked at outcomes by geographic area, the researchers noted that taselisib provided more benefit to study participants who received treatment in North America and Europe, where cancer worsening was delayed by a median of 3.5 months (7.9 with taselisib plus fulvestrant vs. 4.5 months with only fulvestrant). In other countries including Eastern Europe and Latin America, taselisib appeared to provide very little or no added benefit. More research is needed understand the reasons for this discrepancy.
Study at a Glance

<table>
<thead>
<tr>
<th>Disease</th>
<th>Advanced, ER+, HER2- Breast Cancer</th>
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<tbody>
<tr>
<td>Trial Phase, Type</td>
<td>Phase III, Randomized</td>
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<tr>
<td>Patients on Trial</td>
<td>516</td>
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<tr>
<td>Intervention Tested</td>
<td>Fulvestrant plus placebo vs. fulvestrant plus taselisib</td>
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<tr>
<td>Primary Finding</td>
<td>mPFS 5.4 months with placebo vs. 7.4 months with taselisib.</td>
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<tr>
<td>Secondary Finding(s)</td>
<td>ORR 11.9% with placebo vs. 28% with taselisib.</td>
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View the full abstract.

For your readers:

- Guide to Breast Cancer
  (Cancer de mama)
- Guide to Metastatic Breast Cancer
  (Cancer de mama metastásico)
- Understanding Targeted Therapy
  (Qué es la terapia dirigida)

View the disclosures for the 2018 ASCO Annual Meeting News Planning Team.

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