Multiple **PIK3CA** mutations in cis increase oncogenicity and sensitivity to PI3Kα inhibitors

FoundationOne®Liquid detected multiple mutations of PIK3CA, which are frequent in breast cancer patients and have shown increased response to targeted therapy, as published recently in Science. To see full publication please visit: [https://science.sciencemag.org/content/366/6466/714.full](https://science.sciencemag.org/content/366/6466/714.full) or reference Vasan et al, Science.

"The common practice of sequencing only certain single-nucleotide variants or some but not all exons across a gene likely underestimates the frequency of multiple mutations in PIK3CA mutant cancers at <1%.^2^3 In fact, the true frequency is ~10 to 19%, which translates to a clinically meaningful number of patients who may derive additional benefit from this targeted therapy."

— Neil Vasan et al., in Science

**508 patients** received FoundationOne Liquid testing in the SANDPIPER phase III clinical trial

**339**  
339 patients tested positive for **PIK3CA** mutations

**80%**  
80% with one **PIK3CA** mutation

**20%**  
20% with 2 or more **PIK3CA** mutations

**SANDPIPER Phase III Trial Details**

Efficacy of taselisib (GDC-0032) in combination with fulvestrant, versus a placebo and fulvestrant, in a metastatic ER+/HER2- breast cancer patient population enriched with **PIK3CA** mutations.

**Placebo** vs. **Taselisib** in **PIK3CA** mutant ctDNA population

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Objective response rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (n=23)</td>
<td>10</td>
</tr>
<tr>
<td>Taselisib (n=43)</td>
<td>30</td>
</tr>
</tbody>
</table>

* p<0.05

**Placebo** vs. **Taselisib** in **PIK3CA** mutant ctDNA population

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<thead>
<tr>
<th>Treatment group</th>
<th>Objective response rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (n=80)</td>
<td>8</td>
</tr>
<tr>
<td>Taselisib (n=193)</td>
<td>30</td>
</tr>
</tbody>
</table>

NS = not significant
**Why FoundationOne®Liquid?**

FoundationOne Liquid is a laboratory developed comprehensive genomic profiling test that can detect multiple PIK3CA mutations in your ER+/HER2- locally advanced or metastatic breast cancer patients as demonstrated in this publication.

Foundation Medicine is the only company with a proven portfolio of comprehensive genomic profiling tests – from a blood draw or tissue biopsy – that has demonstrated clinical utility for patients with advanced breast cancer.

- Fast results in less than two weeks
- Tests include guideline-recommended genes in Breast Cancer
- Decision support services included with every case

The SANDPIPER trial employed investigational use of the FoundationOne Liquid assay. FoundationOne Liquid is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine.

**References**

2. L.H. Saal et al., Cancer Res. 65, 2554-2559 (2005).