<table>
<thead>
<tr>
<th>NCT01623349</th>
<th>Phase I Study of the Oral PI3kinase Inhibitor BKM120 or BYL719 and the Oral PARP Inhibitor Olaparib in Patients With Recurrent Triple Negative Breast Cancer or High Grade Serous Ovarian Cancer</th>
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</thead>
<tbody>
<tr>
<td><strong>Phase</strong></td>
<td>I</td>
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<tr>
<td><strong>Drug Class</strong></td>
<td>PI3K, AKT, mTOR Inhibitors: PI3K Inhibitor</td>
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<tr>
<td><strong>Drug Name</strong></td>
<td>Buparlisib</td>
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<tr>
<td><strong>Alternate Drug Names</strong></td>
<td>BKM120</td>
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<tr>
<td><strong>Eligible Participant</strong></td>
<td>Advanced solid tumors</td>
</tr>
<tr>
<td><strong>Patients Enrolled</strong></td>
<td>118 (46 ovarian for Ola+Bup)</td>
</tr>
<tr>
<td><strong>Therapy Setting</strong></td>
<td>Recurrence</td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td>Open Label, Non-Randomized</td>
</tr>
<tr>
<td><strong>Endpoints</strong></td>
<td>Recommended Phase 2 Dose (RP2D), ORR evaluated per RECIST, DCR</td>
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<tr>
<td><strong>Biomarkers</strong></td>
<td>BRCA1/2 germline mutations</td>
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</tbody>
</table>
| **Efficacy** | **RP2D:** Buparlisib 50 mg QD and Olaparib 300 mg BID  
Results for all doses: **ORR:** 29% (12 PR, n=41), **DCR** (>6 months): 36%  
**Exploratory subgroup analysis:**  
**ORR** (platinum-sensitive): 32% (6 PR, n=19), **ORR** (platinum-resistant): 27% (6 PR, n=22) |
| **Clinically Significant Adverse Events** | Dose Limiting Toxicities: depression (n=1), transaminitis (n=2), hyperglycemia (n=1)  
Serious AE: none  
Grade 3-4 AE: none  
36% and 28% of patients experienced low grade depression or anxiety, respectively |
| **Conclusion** | Promising activity in gBRCA MUT and gBRCA WT |
Legend

Therapy Setting
First-line – Therapy given to patients on initial diagnosis of disease as the first, best treatment option.
Maintenance – Therapy given to patients to help keep cancer from coming back after it has responded to therapy.
Recurrence – Therapy given to patients in whom disease has returned after prior therapy.

Study Design
Randomized -- A study in which participants are assigned by chance to the separate study groups.
Non-randomized -- A study in which participants are NOT assigned by chance to the separate study groups.

Efficacy Endpoints
PFS: Progression-Free Survival — length of time during and after treatment during which the cancer does not get worse (usually reported as the time when the cancer for half—or median-- of the people in the treatment group gets worse).
OS: Overall Survival — length of time from the start of treatment that patients are still alive (usually reported as the time when half--or median-- of the people in the treatment group are still alive).
CR: Complete Response -- The disappearance of all signs of cancer in response to treatment.
SD: Stable Disease Response -- Cancer that is neither decreasing nor increasing in extent or severity.
ORR: Objective Response Rate -- Sum of complete and partial tumor responses to treatment, divided by the number of patients evaluated.
DCR: Disease Control Rate -- Sum of complete, partial and stable disease tumor responses to treatment, divided by the number of patients evaluated.
HR: Hazard Ratio -- measures survival in the treatment group compared to the control group. An HR = 1 means that there is no difference in survival between the groups. An HR < 1 means that the treatment group has a lower risk of death compared to the control group. Range in parentheses is 95% Confidence Interval (CI).
RECIST: Response Evaluation Criteria in Solid Tumors -- Set of rules, based on measurements of the change in tumor size that define when cancer patients improve, stabilize, or worsen during a treatment regimen.
CA125: GCIG CA125 Criteria -- Set of rules, based on measurements of the CA125 biomarker level that define when cancer patients improve, stabilize, or worsen during a treatment regimen

Clinically Significant Adverse Events (Based on National Cancer Institute--Common Terminology Criteria for Adverse Events (CTCAE)
AE: Adverse events -- any undesirable experience associated with the use of a drug
SAE: Serious adverse events – untoward event associated with drug treatment e.g., death, life-threatening, requiring of hospitalization, persistent or significant incapacity; usually graded from 1-5.