Thank you for your inquiry, please see the following page for the information you requested.

This content includes a QR code giving access to supportive information for the study.
**Background**

- Approximately 5–10% of breast cancers contain a germline mutation in the BRCA1 or BRCA2 tumor suppressor genes.
- In the phase 3 OlympiAD trial (NCT02212062), olaparib, a PARP inhibitor, showed a significant improvement in progression-free survival (PFS) compared with chemotherapy in patients with a germline BRCA mutation (gBRCAm), human epithelial growth factor receptor 2 (HER2)-negative metastatic breast cancer.
- The LUCY trial (NCT03029042) is evaluating the clinical effectiveness of olaparib in patients with gBRCAm or somatic BRCA mutation (sBRCAm), HER2-negative metastatic breast cancer in a real-world setting, to help inform and guide clinical practice.

**Methods**

- **Study Design and participants**
  - LUCY is an open-label, single-arm, multicenter, international, phase 3b trial in patients with BRCA-mutated, HER2-negative metastatic breast cancer.
  - **Eligible patients:**
    - Metastatic breast cancer with confirmed, gBRCAm or sBRCAm
    - No previous treatment with PARP inhibitor
    - No prior chemotherapy for metastatic disease
    - ECOG performance status 0–2
    - Age ≥ 18 years
    - Eastern Cooperative Oncology Group (ECOG) performance status 0–2
    - At least 1 previous platinum-based chemotherapy + endocrine therapy (if hormone receptor–positive)
    - Serum creatinine ≤ 1.5 mg/dL
    - Adequate bone marrow, liver, and pulmonary function

- **Primary endpoint:** investigator-defined assessment of PFS.
- **Key secondary endpoints included:**
  - Investigator-assessed clinical response rate (proportion of patients assessed as responding on at least one assessment of clinical response (DoCR) were to first subsequent treatment or death (DFS), time to study discontinuation or death (TDS), 3-year overall survival (OS), previously untreated disease.

**Results**

- **Subgroup analysis of PFS**
  - Median PFS was consistent across the patient subgroups.
  - The investigator-assessed median PFS was 8.11 months (95% confidence interval [CI]: 6.93, 8.67).
  - At the data cut-off for the interim analysis (September 23, 2019), there were 166 PFS events in the gBRCAm cohort (65.9% maturity).

- **Data are presented as n (%) unless otherwise stated.**

- **Table 1. Baseline characteristics (full analysis set).**

- **Table 2. Key secondary endpoints (full analysis set).**

- **Table 3. Summary of AEs (full analysis set).**

**Conclusions and key messages**

- **Interim data from the LUCY trial support the clinical effectiveness of olaparib in the real-world setting in patients with gBRCAm, HER2-negative metastatic breast cancer.**
  - Clinical efficacy assessed by median PFS was consistent with that reported in the phase 3 OlympiAD study (8.1 and 7.0 months, respectively).
  - PFS was similar across main patient subgroups.
  - AEs were consistent with the known safety profile of olaparib.

- Olaparib was generally well tolerated, providing a chemotherapy-free alternative treatment for patients with gBRCAm, HER2-negative metastatic breast cancer.

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**References**


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