# Phase 2 Study of Pamiparib in Chinese Patients (pts) With Advanced Ovarian Cancer (aOC)

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**Background:** Pamiparib, an investigational, selective inhibitor of PARP1/2, has PARP-DNA complex trapping capabilities. The first-in-human study (NCT02361723) established the pamiparib phase 2 dose as 60 mg po BID. Responses were reported in *BRCA* mutated or wild-type and platinum-sensitive/resistant aOC. Here we present phase 2 results from an ongoing phase 1/2 study in Chinese pts with advanced solid tumors (NCT03333915).
**Methods:** Patients with platinum-sensitive (cohort 1) and platinum-resistant (cohort 2) aOC were enrolled. Patients with known/suspected deleterious germline *BRCA1/2* mutation and ≥2 prior lines of chemotherapy were eligible. The primary endpoint was objective response rate (ORR) assessed by an independent review committee ($ORR_{IRC}$) per RECIST v1.1.
**Results:** As of 2 Feb 2020, 113 pts (cohort 1, n=90; cohort 2, n=23) were enrolled. Median age was 54 yr (range: 34-79), 25.6% (n=29) of pts had received ≥4 prior systemic chemotherapy lines, and 54.0% (n=61) of pts had an ECOG score of 1 at study entry. At data cutoff, median follow-up was 12.2 mo (range: 0.2-21.5). Across both cohorts, pamiparib showed preliminary antitumor activity (**Table**). In cohort 1, confirmed $ORR_{IRC}$ was 64.6%, median DoR was 14.5 mo (95% CI, 11.1-NE), progression-free survival (PFS) was 15.2 mo (95% CI, 10.35-NE), and median overall survival (OS) was not yet mature. In cohort 2,

confirmed $ORR_{IRC}$ was 31.6%, median DoR was 11.1 mo (95% CI, 4.21-NE), median PFS was 6.2 mo (95% CI, 4.11-NE), and median OS was 13.6 mo (95% CI, 7.13-NE). Overall, the most common treatment-related AE was anemia (any grade, 89%; grade ≥3, 42%); following a per-protocol proposed dose modification algorithm, the incidence of grade ≥3 anemia was reduced to 25.6%.

**Conclusions:** Promising antitumor activity was observed in pts with platinum-sensitive/resistant aOC. Pamiparib was generally tolerated, with no new safety signals. Pamiparib is being evaluated as monotherapy and combination therapy for other solid tumors.

| Efficacy-Evaluable Population | Cohort 1 (n=82) | Cohort 2 (n=19) |
|---|---|---|
| **Best overall response, n (%)** | | |
| Complete response | 8 (9.8) | 0 (0) |
| Partial response | 45 (54.9) | 6 (31.6) |
| Stable disease | 25 (30.5) | 12 (63.2) |
| Progressive disease | 4 (4.9) | 1 (5.3) |
| **Objective response rate, % (95% CI)** | | |
| Confirmed | 64.6 (53.3-74.9) | 31.6 (12.6-56.6) |
| **Disease control rate, % (95% CI)** | 95.1 (88.0-98.7) | 94.7 (74.0-99.9) |
| **Clinical benefit rate, % (95% CI)** | 74.4 (63.6-83.4) | 52.6 (28.9-75.6) |
| **Time to response, median mo (range)** | 1.68 (1.3-6.3) | 1.38 (1.2-1.4) |
| **Duration of response, median mo (95% CI)** | 14.5 (11.1-NE) | 11.1 (4.21-NE) |
| **PFS, median mo (95% CI)** | 15.2 (10.35-NE) | 6.2 (4.11-NE) |

**Abbreviations:** NE, not estimable; PFS, progression-free survival.