

# Niraparib Phase 1 Data Summary



LEERINK SWANN

- Efficacy
  - Overall activity (60pts in advanced solid tumors, 20pts in platinum resistant ovarian cancers)
    - PR – 15% (12/80), 10 ovarian and 2 breast
    - SD – 30% (24/80), ovarian, breast, lung
    - Clinical activity shown at 80mg
  - Clinical activity in platinum resistant ovarian cancer
    - PR – 26% (10/39); SD – 33% (13/39)
    - PR – 37% (7/19), SD – 26% (5/19) in BRCA mutant positive patients
- Safety
  - Main adverse events were nausea, fatigue and constipation
  - Drug related SAE – 11.3% (9/80)
  - Dropout due to drug related AE – 7.5% (6/80)
  - Dose limiting toxicity – thrombocytopenia, resolved when drug was discontinued
  - MTD – 300mg once daily