Voreloxin, a novel topoisomerase II inhibitor and DNA intercalator. Voreloxin has a Validated Mechanism of Action with Distinct Advantages Over Anthracyclines

Voreloxin is active in ovarian cancer biopsies, including platinum-resistant samples. The efficacy of voreloxin in platinum-resistant ovarian cancer biopsies was also low in Cohort B (5%), which supported dose escalation.

**STUDY DESIGN AND OBJECTIVES**

**Primary Objective:** ORR using RECIST criteria

**Secondary Objectives:** Safety and median PFS

**Treatment:** Voryloxin IV injection within 10 minutes

Dose cohorts:

- Cohort A (N=65) 48 mg/m² q3weeks
- Cohort B (N=35) 60 mg/m² q4weeks
- Cohort C (currently enrolling to N=110)

**Response**

- Partial or Complete Response
- Stable Disease
- Progressive Disease

**Arrangement**

- 1°: Carboplatin-resistant ovarian tumor biopsies.
- 2°: Carboplatin-sensitive ovarian tumor biopsies.
- 3°: Carboplatin-sensitive ovarian tumor biopsies.

**RESIDUAL DRUG EYEWASH**

- **Prior Tx**
  - Carboplatin
  - Doxorubicin and etoposide

**RESPONDER PROFILES**

Profiles of Cohort A (48 mg/m²) Responders

- **Responder Characteristics**
- **Best Response**
- **Cycles**

Cohort A (48 mg/m²) Responders

- **Prior Tx**
  - Carboplatin

**PFS**

- **Cohort A**
  - 2nd line: Carbo/Taxol
  - 1st line: Carbo/Gemcitabine

**Cycles**

- **Cohort A**
  - 2nd line: Carbo/Taxol

**Cohort B (60 mg/m²) Responders**

- **Prior Tx**
  - Carboplatin

**PFS**

- **Cohort B**
  - 2nd line: Carbo/Taxol

**Cycles**

- **Cohort B**
  - 2nd line: Carbo/Taxol

**Cohort C**

- **Prior Tx**
  - Carboplatin

**PFS**

- **Cohort C**
  - 2nd line: Carbo/Taxol

**Cycles**

- **Cohort C**
  - 1st line: Carbo/Taxol

**Additional Information**

- **Number associated with target lesion bar is the number of cycles the patient has received as of October 16, 2008.**