PHASE I OF IRINTECAN (IR) AND CISPLATIN (CP) IN COMBINATION WITH FELVIC RADIOThERAPY IN THE TREATMENT (TT) OF ADVANCED CERVICAL CANCER (ACC): A GINECO TRIAL


with French Avertis-Smof support

ABSTRACT 5054

Background: Chemotherapy with weekly CP has become standard for ACC treatment. Combining CP with another systemic agent in ACC such as a HT may increase its activity.

Methods: Treatment consisted of 1-weekly cycles with escalating dose of IR and fixed dose of CP (20 mg/m² administered as a single-pellet radiopharmaceutical: CPT-11 O3). BC: Primordial history of cervical carcinoma or cervical carcinoma in situ and ACC. Liver metastases (PM) were allowed. Adverse events were recorded according to the CTCAE v4.03.

RESULTS

INTRODUCTION

The following irinotecan dose levels were planned:

- Dose Escalation: 0, 1, 2, and 3 mg/m².
- The following irinotecan dose levels were planned:

METHODS (cont’d)

- Bi-weekly dose levels

RESULTS

15 patients (10) were accrued 6 pts level 1 (10 mg/m²), 3 pts level 2 (20 mg/m²), and 2 pts level 3 (30 mg/m²).

RESULTS (cont’d)

Toxicity Table 2: Dose-Limiting Toxicity (No. of patients)

- Grade 3 radiation hepatitis: 1
- Grade 4 radiation pneumonitis: 1
- Grade 3 radiation colitis: 1
- Grade 3 radiation enteritis: 1
- Grade 3 radiation dermatitis: 2

- Grade 3 radiation pneumonitis: 1
- Grade 3 radiation enteritis: 1
- Grade 3 radiation dermatitis: 2

- Grade 3 radiation pneumonitis: 1
- Grade 3 radiation enteritis: 1
- Grade 3 radiation dermatitis: 2

Efficacy

- All patients were evaluable for response: 3 pts achieved a partial clinical response and 5 pts partial regression.

CONCLUSION

- The recommended dose for future phase II studies, in advanced cervical cancer, is 20 mg/m² of irinotecan (IR) weekly in combination with cisplatin (CP) (3 mg/m² weekly) with pelvic radiotherapy.

- The Maximum Toleraed Dose (MTD) is reached when 2/3 of the patients experience a CT at the maximum tolerated level.

- The recommended dose is 10 mg/m² evidencing the level of the MTD.

- The trial was conducted according to the Modified Continual Reevaluation Method (MCRM) by the University of Minnesota (1994).