



## A phase II evaluation of mifepristone in the treatment of recurrent or persistent epithelial ovarian, fallopian or primary peritoneal cancer: A gynecologic oncology group study

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### ABSTRACT

**Objective.** To evaluate the effectiveness and toxicity of mifepristone in patients with ovarian, peritoneal and fallopian tube cancers.

**Methods.** Patients with confirmed epithelial ovarian, peritoneal and fallopian tube cancers which were persistent or recurred in less than 1 year after primary chemotherapy were entered into this study. Patients were given mifepristone 200 mg by mouth daily for a 28 day cycle. The medication was stopped for unacceptable toxicity or tumor progression.

**Results.** Twenty-four patients were entered into the study. Twenty-two patients were evaluable for response. Only one patient had a partial response for a response rate of only 4.5% (90% confidence interval: 0.2%, 19.8%).

**Conclusion.** Mifepristone has not proven to be an effective agent in the treatment of patients with recurrent or persistent ovarian, peritoneal and fallopian tube cancers.

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### Introduction

Of all gynecologic malignancies, epithelial ovarian cancer (EOC) has the highest mortality rate. Statistics show that 1 out of 70 women will develop ovarian cancer and 1 out of 100 will die from this cancer. The five-year survival for advanced stage is 15–20% [1]. The standard treatment of a combination of a platinum and taxane drug has a median disease-free interval of 18 months and a median survival of 38 months [2]. The recent addition of intraperitoneal chemotherapy has increased the median survival to over 60 months in optimally debulked Stage III patients [3]. Although second line chemotherapy has improved the length of patient survival, it has been ineffective in increasing the cure rate, especially in patients whose recurrence is less than 1 year from the end of primary chemotherapy.

Steroid hormones play an important role in the control of normal and neoplastic ovarian surface epithelium [4]. Mifepristone is a

synthetic hormone antagonist that binds to the progesterone but not to the estrogen receptors. Clinically, progesterone receptor antagonists have been used in trials for menstrual regulation, induction of labor and for the treatment of breast cancer and meningiomas.

Rose and Barnea showed that mifepristone inhibits the growth of ovarian epithelial cells *in vitro* [5]. Rocereto et al. treated 44 women with recurrent/persistent ovarian cancer whose tumors had become resistant to platinum and paclitaxel with mifepristone, 200 mg orally on a daily basis [6]. Of the 34 women who were evaluable for response, 9 (26.5%) had a response, 3 (9%) complete and 6 (17.5%) partial. In this study, only patients who completed one course of treatment (28 days) were considered evaluable for response.

The present study was conducted to further evaluate the effectiveness and toxicity of mifepristone in patients with ovarian, peritoneal and fallopian tube cancers whose tumor was persistent after or recurred in less than 1 year after the end of their primary treatment.

### Methods

This group wide multi-institutional phase II trial was open for patient entry from May 2007 to October 2007. Eligible patients had to

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