Control/Tracking Number: 08-AB-32453-ASCOAM
Activity: Abstract Submission
Current Date/Time: 1/6/2008 10:21:25 PM

A feasibility/phase II study of UFT/LV and irinotecan (TEGAFIRI) in advanced or metastatic colorectal cancer (CRC) (OGSG 0304)

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Abstract:
Background: This is a feasibility/phase II trial of TEGAFIRI with maximum dose confirmed in Japan. Objectives: To document the toxicity and define the objective response rate; and determine progression free and overall survival.
Methods: Pts with advanced or metastatic CRC received: UFT 300mg/m2, LV 75 mg/body, CPT-11 150mg/m2 (UFT and LV given on d1-14, CPT-11 on d1, every 3 wks). Eligibility: ECOG PS 0-1, adequate bone marrow/liver function, serum creatinine level < institutional normal value.
Results: 18 pts enrolled, 17 evaluable for toxicity and response; 1 patients recalled chemotherapy upon registration. Characteristics: 61% male, median age 63.5 yrs (51-71). 72% PS 0, 78% 1st line. 186 cycles have been delivered. The common grade 3 to 4 toxicities were neutropenia (35.3%), leukopenia (29.4%), diarrhea (5.9%), anorexia (5.9%), vomiting (5.9%) and dizziness (5.9%). There were no episode of febrile neutropenia. No death occurred on treatment: Overall RR was 41% (7/17: 1 CR+ 6 PR). Median survival is 511+ days. One-year survival rate is 65+%.
Conclusion: The combination therapy of UFT/LV and irinotecan (TEGAFIRI) for patients with advanced or metastatic CRC seems to be effective and well tolerated in Japan. The survival period is being assessed and updated data will be present at the meeting.
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Author Disclosure Information: **Y. Miyake**, None; **H. Ishida**, None; **M. Fukunaga**, None; **T. Kato**, None; **Y. Watanabe**, None; **H. Takemoto**, None; **H. Furukawa**, None.

Topic Category (Complete): Colorectal Cancer (including liver metastases)
Keyword (Complete): colorectal cancer ; clinical trials
Sponsor (Complete):
Additional Information I (Complete):
Type of Trial: Phase II
Research Category: Clinical
Trial Accrual: No
Funding: Other
Funder Name: : Osaka gastrointestinal cancer chemotherapy study group
Grant Fundng: No
Type of Grant: Not Applicable

Additional Information II (Complete):
Trial Participants over the age of 65: No
I Agree to ASCO Abstract Policies: Yes
I Agree to Present: Yes
Withdraw My Abstract if Not Selected: No
Abstract selected for presentation at the 2008 Gastrointestinal Cancers Symposium: No
Abstract selected for presentation at the 2008 Genitourinary Cancers Symposium: No
Abstract presented at the 2007 Breast Cancer Symposium: No
Merit Award: No

Late Breaking (Complete):
I intend to submit a late-breaking abstract: No

Attached Files:
No Files Attached
Status: Complete

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