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Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company: sanofi-aventis

ClinialTrials.gov Identifier: NCT00611507

Study Code: L_8107

Generic drug name: oxaliplatin

Date: 26 February 08

Title of Study:
A Phase II study of Oxaliplatin in association with 5FU and Folinic Acid in the treatment of subjects with Non-Surgical or Advanced Metastatic Gastric Cancer.

Investigators: Dr. Carlos Vargas-Baez

Study centre(s): Fundación Santa Fé
Calle 119, Bogotá DC, Colombia

Publication : NA

Studied period (years):
date of first enrolment : NOV-2002

date of last completed : APR-2004

Phase of development: Phase II, single arm.

Objectives:
Primary Study Endpoint:
Response rate – RECIST criteria (unidimensional)

Secondary Endpoint(s):
Progression-free Survival (PFS).
Overall survival (OS)
Tolerability/Safety

Methodology: Phase II study, only one arm.

Number of patients (planned and analyzed):
Planned: 40 patients.
Analyzed: 21 patients.
Population:

- Histologically proven Gastric Adenocarcinoma.
- Disease measured in a unidimensional manner.
- Primary or recurrent gastric cancer after local and/or systemic treatment with a post-surgical period of at least 4 weeks and a minimum period of post-adjuvant chemotherapy of 6 months.

Diagnosis and main criteria for inclusion:

1. Histologically proven gastric or gastroesophagic junction adenocarcinoma
2. Measurable disease at least in a unidimensional manner. If a unique metastasis constitutes the only disease symptom, histological confirmation will be required.
3. Metastatic or locally non-surgical primary gastric cancer
4. Recurrent gastric cancer after local and/or systemic treatment with a post-surgical period of at least 4 weeks, a post-adjuvant chemotherapy period or a neo-adjuvant chemo-radiotherapy of at least 6 months.
5. –Serum bilirubin< 2 mg/dl
   -Serum creatinine ≤ 2 times normal superior limit
   -Absolute neutrophil count ≥ 2000/dl
   -Platelet count ≥ 100000/dl
   -Hemoglobin ≥ 10 g/dl
   -AST/ALT ≤ 2.5 times normal superior institutional limit
   -Alkaline phosphatase ≤ 5 times the normal superior institutional limit
6. Age > 18 years
7. Performance Status ECOG 0-2
8. Written informed consent signed and dated.

Test product, dose and mode of administration :

1. Presentations:

- Oxaliplatin: Oxaliplatin is presented as a white-colored powder dried by freezing, packed in crystal vials. It is reconstituted adding water for injection or 5% glucose solution, and then diluting it in infusion solution.
- 5-Fluorouracil, Folinic acid: marketed presentation available.

2. Dose Regimen:

5FU 500 mg/m² per week in IV bolus infusion during 30 min
AF 20mg/m²/ week in infusion, during 10-20 minutes prior 5FU infusion;
Eloxatin 85 mg/m² as IV infusion 2-6 hours, every 2 weeks.
Three weeks of treatment, one week rest.

Duration of treatment:

The patient will continue the study treatment until disease progression, non-acceptable toxicity, patient desire to withdraw or treatment delay > 3 weeks.

Criteria for evaluation:

Efficacy:

- Assessed response according to RECIST criteria.

  Complete Response (CR): absence of all targeted-lesions, determined by 2 observations performed during a time not superior to 4 weeks with a confirmed CR.

  Partial Response (PR): At least 30% reduction in the sum of the major diameter of the targeted-lesions, taking as reference, the sum of the initial/baseline diameter.

  Progressive Disease (PD): a minimum 20% increase in the sum of the major diameter of the targeted-lesions, taking as reference the minor sum of the major diameter recorded at baseline or beginning of treatment, or the appearance of one or more lesions.

Stable Disease (SD): decrease which is not enough to qualify as partial response, or an increase which is not enough to qualify as progressive disease, taking as reference the minor sum of the major diameter at baseline or beginning of treatment

- Assessed progression-free survival of the population with the Kaplan Meier method.
- Assessed overall survival in the population, with the Kaplan Meier method.

Safety:

- Assessed safety using the NCI-CTC criteria, version 2.

Statistical methods:
Statistical analysis will be done according to intention-to-treat. Missing data will be considered as failures or no-responses.
Statistical analysis will be only of descriptive nature.
Descriptive statistics will be provided according to the variables' nature:
Size, mean, standard deviation, minimum and maximum values, median and quartiles for quantitative variables.
Size and absolute frequencies for qualitative variables.
The time for the events will be illustrated with Survival curves using the Kaplan-Meier method.

SUMMARY

Twenty one (21) patients were included in the study, 71% (15) of patients completed the study and 4 of them died; 29% (6) of the patients were lost during follow-up.

Sixty two percent (62%) (13) of the patients were males and 38% (8) females. Age range between 35 to 78 years and an average age of 57 years.

EFFICACY RESULTS:
According to RECIST criteria, 62% (13) of the patients remained stable, 33% (7) presented partial response and 5% (1) progressive disease. There were no patients with complete response.

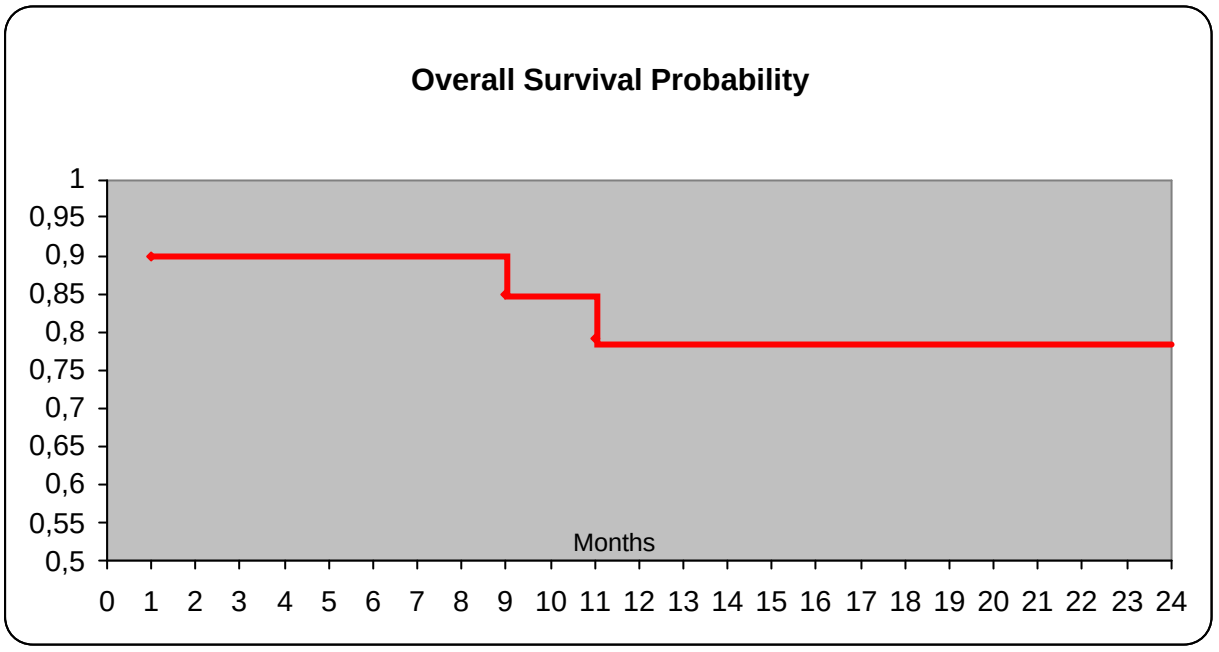
Global survival at the end of the first month of treatment was 90%, 85% at nine months and 79% at eleven months, the same percentage was seen until the end of follow-up (24 months). (See graph 1).

SAFETY RESULTS:
A total of 120 cycles were given to the patients during the study period, being hemoglobin disturbance the adverse event of major incidence in 44% of the cycles and according to NCI-CTC classification, 87% grade 1, 11% grade 2 and 2% grade 3. Platelet disturbance was observed in 19% of the cycles, a 100% being grade 1, and Neutrophil disturbance was observed in 5% of the cycles, 83% grade 1 and the remaining, grade 2.

Nausea was evidenced in 29% of the cycles, 66% grade 1 and 33% grade 2. Vomit in 23%, 56% grade 1 and 44% grade 2, and diarrhea was observed in 3% of the cycles.

Pain was referred by patients in 27% of the cycles, 66% grade 1, 31% grade 2 y 3% grade 3; sensory neuropathy grade 1 was seen in 4% of the cycles, motor neuropathy in 3% of the cycles, grade 1 and 2.

Date of report: 30-JUNE-2007



Graph 1. ***Survival estimation in months using the Kaplan-Meier method for Non-Surgical or Metastatic Advanced Gastric Cancer in patients treated with Oxaliplatin in association with 5FU and Folinic Acid.***