Claims

1. Use of liposomal irinotecan in the preparation of a medicament for treating metastatic adenocarcinoma of the pancreas in a human patient who has not previously received chemotherapy to treat the metastatic adenocarcinoma of the pancreas, wherein the medicament is to be administered intravenously in combination with oxaliplatin, leucovorin, and 5-fluorouracil as an antineoplastic therapy to the patient once every two weeks, the antineoplastic therapy consisting of:
   a. liposomal irinotecan in a dose providing the equivalent of 50 mg/m^2 of irinotecan free base,
   b. 60 mg/m^2 oxaliplatin,
   c. 200 mg/m^2 of the (l)-form of leucovorin or 400 mg/m^2 of the (l+d) racemic form of leucovorin, and
   d. 2,400 mg/m^2 5-fluorouracil,

   to treat the metastatic adenocarcinoma of the pancreas in the human patient.

2. The use of claim 1, wherein the 5-fluorouracil is to be administered as an infusion over 46 hours.
3. The use of claim 1 or claim 2, wherein the leucovorin is to be administered immediately prior to the 5-fluorouracil.
4. The use of any one of claims 1-3, wherein the liposomal irinotecan, oxaliplatin and leucovorin are to be administered on days 1 and 15 of a 28-day treatment cycle.
5. Use of liposomal irinotecan in the preparation of a medicament for treating metastatic adenocarcinoma of the pancreas in a human patient who has not previously received chemotherapy to treat the metastatic adenocarcinoma of the pancreas, wherein the medicament is to be administered intravenously in combination with oxaliplatin, leucovorin, and 5-fluorouracil as an antineoplastic therapy to the patient once every two weeks, the antineoplastic therapy consisting of:

a. liposomal irinotecan in a dose providing the equivalent of 50 mg/m^2 of irinotecan free base,
b. 60 mg/m^2 oxaliplatin,
c. 200 mg/m^2 of the (l)-form of leucovorin or 400 mg/m^2 of the (l+d) racemic form of leucovorin, and
d. 2,400 mg/m^2 5-fluorouracil,

to treat the metastatic adenocarcinoma of the pancreas in the human patient, wherein the liposomal irinotecan, oxaliplatin, and leucovorin are to be administered on days 1 and 15 of a 28-day treatment cycle.

6. The use of any one of claims 1-5, wherein the liposomal irinotecan is to be administered as an infusion over a total of about 90 minutes.
7. The use of any one of claims 1-6, wherein the liposomal irinotecan is to be administered, followed by the oxaliplatin, followed by the leucovorin, followed by the 5-fluorouracil.
8. Use of liposomal irinotecan in the preparation of a medicament for treating metastatic adenocarcinoma of the pancreas in a human patient who has not previously received chemotherapy to treat the metastatic adenocarcinoma of the pancreas, wherein the medicament is to be administered intravenously in combination with oxaliplatin, leucovorin, and 5-fluorouracil as an antineoplastic therapy to the patient once every two weeks, the antineoplastic therapy consisting of:
a. liposomal irinotecan in a dose providing the equivalent of 50 mg/m^2 of irinotecan free base,
b. 60 mg/m^2 oxaliplatin,
c. 200 mg/m^2 of the (l)-form of leucovorin or 400 mg/m^2 of the (l+d) racemic form of leucovorin, and
d. 2,400 mg/m^2 5-fluorouracil,

to treat the metastatic adenocarcinoma of the pancreas in the human patient, wherein the liposomal irinotecan is to be administered, followed by the oxaliplatin, followed by the leucovorin, followed by the 5-fluorouracil.

9. The use of any one of claims 1-8, wherein the administration of the oxaliplatin begins 2 hours after completing each administration of the liposomal irinotecan.

10. Use of liposomal irinotecan in the preparation of a medicament for treating metastatic adenocarcinoma of the pancreas in a human patient who has not previously received chemotherapy to treat the metastatic adenocarcinoma of the pancreas, wherein the medicament is to be administered intravenously in combination with oxaliplatin, leucovorin, and 5-fluorouracil as an antineoplastic therapy to the patient once every two weeks, the antineoplastic therapy consisting of:

    a. liposomal irinotecan in a dose providing the equivalent of 50 mg/m^2 of irinotecan free base,

    b. 60 mg/m^2 oxaliplatin,

    c. 200 mg/m^2 of the (l)-form of leucovorin or 400 mg/m^2 of the (l+d) racemic form of leucovorin, and

    d. 2,400 mg/m^2 5-fluorouracil,

to treat the metastatic adenocarcinoma of the pancreas in the human patient, wherein the liposomal irinotecan, oxaliplatin and leucovorin are to be administered on days 1 and 15 of a 28-day treatment cycle, wherein the liposomal irinotecan is to be administered, followed by the oxaliplatin, followed by the leucovorin, followed by the 5-fluorouracil, and wherein the administration of the oxaliplatin begins 2 hours after completing each administration of the liposomal irinotecan.

11. The use of any one of claims 4, 5, or 10, wherein administration of the 5-fluorouracil is initiated beginning on days 1 and 15 of a 28-day treatment cycle.

12. The use of any one of claims 1-11, further comprising dexamethasone and a 5-HT3 antagonist or other anti-emetic to be administered prior to the antineoplastic therapy.

13. The use of any one of claims 1-12, wherein the liposomal irinotecan comprises irinotecan sucrose octasulfate encapsulated in liposomes.

14. The use of any one of claims 1-13, wherein the liposomal irinotecan comprises irinotecan encapsulated in liposome vesicles comprising 1,2-

distearoyl-sn-glycero-3-phosphocholine (DSPC), cholesterol, and a polyethyleneglycol-derivatized phosphatidyl-ethanolamine.

15. The use of claim 14, wherein the polyethyleneglycol-derivatized phosphatidyl-ethanolamine is N-(carbonylmethoxypolyethlyene glycol-2000)-1,2-distearoly-sn-glycero-3-phosphoethanolamine (MPEG-2000-DSPE).

16. The use of claim 14, wherein the polyethyleneglycol-derivatized phosphatidyl-ethanolamine is in the amount of approximately one polyethyleneglycol (PEG) molecule for every 200 phospholipid molecules.

17. The use of any one of claims 1-16, wherein the liposomal irinotecan comprises irinotecan sucrose octasulfate encapsulated in liposomes having a unilamellar lipid bilayer vesicle comprising 6.81 mg/ml 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 2.22 mg/ml cholesterol, and 0.12 mg/ml methoxy-terminated polyethylene glycol (MW 2000)-distearoylphosphatidyl ethanolamine (MPEG-2000-DSPE).

18. The use of any one of claims 1-17, wherein the human has not previously received gemcitabine to treat the metastatic adenocarcinoma of the pancreas.