CLAIMS

1) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament for the treatment of solid tumors such as cancer wherein the medicament is to be coadministrated with 5-fluorouracil (5-FU) according to the following regimen:

a) On Day 1, administering an IV bolus containing 10-1000 mg/m^2 (of BSA) of a fluorinated pyrimidine base such as 5-FU , followed, either simultaneously or after a period of 10 min – 4 hours, by

b) administering two or more IV boluses, interspaced by a period of 10 - 60 minutes, each containing 5 – 1000 mg/m^2 [6R]-5,10-methylenetetrahydrofolate, followed by

c) administering a continuous infusion of 5-FU (or an analog or prodrug thereof) over a period of 46 hours, or until the end of Day 2, followed by

d) optionally administering one IV bolus containing 5 – 1000 mg/m^2 (of BSA) [6R]-5,10-methylene-tetrahydrofolate before the end of Day 1, followed by

e) On Day 2, optionally administering one or more IV boluses each containing 5 – 1000 mg/m^2 (of BSA) [6R]-5,10-methylene-tetrahydrofolate,

wherein step b) is optionally repeated up to 4 times on Day 1 with an interval of 10 min –4 hours between each repetition, and wherein step e) is optionally repeated up to 4 times on Day 2 with an interval of between 10 min – 60 min between each bolus being administered, and wherein all steps a) – e) are optionally repeated every 2 weeks for up to eight (8) cycles, i.e. up to sixteen (16) weeks.

2) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to claim 1, wherein the solid tumor is a cancer form selected from colon cancer, stomach cancer, breast cancer, bowel cancer, gallbladder cancer, lung cancer (specifically adenocarcinoma), colorectal cancer (CRC) including metastatic CRC, head and neck cancer, liver cancer, osteosarcoma and pancreatic cancer.

3) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to claim 1 or 2 wherein the two or more IV boluses administered on Day 1 each contains from 20 - 250 mg/m^2 [6R]-5,10-methylenetetrahydrofolate, such as from 30-240mg/m^2, such as from 30-120 mg/m^2 or such

as about 30 mg/m^2 or such as about 60 mg/m^2 or such as about 120 mg/m^2 [6R]-5,10-methylenetetrahydrofolate.

4) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of claim 1 - 3 wherein the solid tumor is a colorectal cancer (CRC) including metastatic CRC.

5) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of claim 1-4, wherein step a) is preceded by administering one or more anticancer drugs on Day 1, either as an IV bolus or as an infusion over a period of 1-4 hours.

6) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of claim 4 or 5 wherein the anticancer drug is selected from oxaliplatin, irinotecan (CPT11) and bevacizumab (Avastin).

7) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of claim 4 or 5 wherein the one or more anticancer drugs administered on Day 1 is oxaliplatin.

8) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of claim 4 or 5 wherein the one or more anticancer drugs administered on Day 1 are oxaliplatin in combination with bevacizumab (Avastin).

9) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of the preceding claims wherein at least two boluses [6R]-5,10-methylenetetrahydrofolate are administered on Day 2 under step e).

10) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to claim 8 wherein up to four boluses [6R]-5,10-methylenetetrahydrofolate are administered with an interval of 20-30 min between each bolus.

11) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to claim 9 wherein up to four boluses [6R]-5,10-methylenetetrahydrofolate are administered with an interval of 20-30 min between each bolus.

12) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of the preceding claims wherein the [6R]-5,10-methylenetetrahydrofolate is employed as a solid form which is soluble in water, such as a lyophilisate or a salt, optionally stabilized by one or more suitable excipients and/or antioxidants such as citric acid or ascorbic acid or salt forms thereof.

13) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of the preceding claims wherein the [6R]-5,10-methylenetetrahydrofolate has a diastereomeric purity of >98% d.e.

14) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to any one of the preceding claims wherein the fluorinated pyrimidine base is selected from 5-FU, 2'-deoxy-5 fluorouridine and 5'-deoxy-5-fluorouridine.

15) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament for use in the prevention or retarding of the progression in a human of solid tumors, including cancer, which comprises performing and repeating steps a) to e) according to any one of claims 1-14 over a total treatment period of at least 8 weeks.

16) Use of [6R]-5,10-methylene-tetrahydrofolate in the manufacture of a medicament according to claim 15, whereby steps a) to e) according to any one of claims 1-13 are performed and repeated over a total treatment period of at least 16 weeks, and whereby no statistically significant progression of said solid tumors is observed between 8 and 16 weeks after initializing treatment.