Claims

1. A pharmaceutical formulation comprising:

gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate, or a pharmaceutically acceptable salt or solvate thereof; and

a platinum-based anticancer agent selected from cisplatin, picoplatin, lipoplatin and triplatin for use in the treatment of cancer.

2. The formulation for use according to claim 1 wherein the platinum-based anticancer agent is cisplatin.

3. The formulation for use according to claim 1 or claim 2, wherein the gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate is gemcitabine-[phenyl-benzoxy-L-alaninyl)]-(S)-phosphate in substantially diastereomerically pure form.

4. The formulation for use according to claim 1 or claim 2, wherein the gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate is a mixture of phosphate diastereoisomers.

5. The formulation for use according to any one of claims 1 to 4, wherein the gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate is in the form of the free base.

6. The formulation for use according to any one of claims 1 to 5, wherein the formulation is to be administered intravenously.

7. The formulation for use according to any one of claims 1 to 6, wherein the cancer is a solid tumour, e.g. a cancer selected from ovarian cancer, bladder cancer, and biliary tract cancer.

8. The formulation for use according to claim 7, wherein the cancer is biliary tract cancer, *e.g.* a cancer selected from gallbladder cancer, distal bile duct cancer, ampullary cancer, hilar cholangiocarcinoma and intra-hepatic cholangiocarcinoma.

9. The formulation for use according to any one of claims 1 to 8, wherein the cancer is relapsed.

10. The formulation for use according to any one of claims 1 to 8, wherein the cancer is metastatic.

11. The formulation for use according to any one of claims 1 to 10, wherein the cancer is refractory, resistant or partially resistant to the platinum-based anticancer agent.

12. The formulation for use according to any one of claims 1 to 9, wherein the cancer is sensitive to the platinum-based anticancer agent.

13. The formulation for use according to any one of claims 1 to 12, wherein the dose of NUC-1031 to be administered at each administration event is between 250 mg/m^2 and 1250 mg/m^2 and the dose of the platinum-based anticancer agent to be administered at each administration event is between 10 mg/m^2 and 200 mg/m^2.

14. Use of gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate, or a pharmaceutically acceptable salt or solvate thereof, in the manufacture of a medicament for the treatment of cancer, wherein the medicament is to be administered to a subject in need thereof in combination with a platinum-based anticancer agent selected from cisplatin, picoplatin, lipoplatin and triplatin.

15. The use according to claim 14, wherein the platinum-based anticancer agent is cisplatin.

16. The use according to claim 14 or claim 15, wherein the gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate is gemcitabine-[phenyl-benzoxy-L-alaninyl)]-(S)-phosphate in substantially diastereomerically pure form.

17. The use according to claim 14 or claim 15, wherein the gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate is a mixture of phosphate diastereoisomers.

18. The use according to any one of claims 14 to 17, wherein the gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate is in the form of the free base.

19. The use according to any one of claims 14 to 18, wherein the medicament is to be administered intravenously.

20. The use according to any one of claims 14 to 19, wherein the cancer is a solid tumour, e.g. a cancer selected from ovarian cancer, bladder cancer, and biliary tract cancer.

21. The use according to claim 20, wherein the cancer is biliary tract cancer, *e.g.* a cancer selected from gallbladder cancer, distal bile duct cancer, ampullary cancer, hilar cholangiocarcinoma and intra-hepatic cholangiocarcinoma.

22. The use according to any one of claims 14 to 21, wherein the cancer is relapsed.

23. The use according to any one of claims 14 to 22, wherein the cancer is metastatic.

24. The use according to any one of claims 14 to 23, wherein the cancer is refractory, resistant or partially resistant to the platinum-based anticancer agent.

25. The use according to any one of claims 14 to 23, wherein the cancer is sensitive to the platinum-based anticancer agent.

26. The use according to any one of claims 14 to 25, wherein the dose of NUC-1031 to be administered at each administration event is preferably between 250 mg/m^2 and 1250 mg/m^2 and the dose of the platinum-based anticancer agent to be administered at each administration event is between 10 mg/m^2 and 200 mg/m^2.

27. The use according to any one of claims 14 to 26, wherein administration of the combination provides an intra-cellular $t_{1/2}$ of dFdCTP of more than 10 hours.

28. The use according to any one of claims 14 to 27, wherein administration of the combination provides an intra-cellular $t_{1/2}$ of dFdCTP of more than 18 hours.

29. A pharmaceutical formulation comprising gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate, or a pharmaceutically acceptable salt or solvate thereof, together with a platinum-based anticancer agent selected from cisplatin, picoplatin, lipoplatin and triplatin, and at least one pharmaceutically acceptable excipient.

30. A kit comprising two separate formulations to be used together, the formulations being:

a first formulation comprising gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate, or a pharmaceutically acceptable salt or solvate thereof, and at least one pharmaceutically acceptable excipient; and

a second formulation comprising a platinum-based anticancer agent selected from cisplatin, picoplatin, lipoplatin and triplatin and at least one pharmaceutically acceptable excipient.