Claims

1. A pharmaceutical formulation comprising:

a protide;

a polar aprotic solvent; and

optionally one or more pharmaceutically acceptable excipients;

wherein the protide is not gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate (NUC-1031).

2. A formulation of claim 1, wherein the polar aprotic solvent is selected from dimethyl acetamide (DMA) dimethylsulfoxide (DMSO) and N-methypyrrolidone (NMP).

3. A formulation of claim 1, wherein the polar aprotic solvent is DMA.

4. A formulation according to any one of claims 1 to 3, wherein the formulation also comprises an aqueous vehicle.

5. A formulation according to claim 4, wherein the aqueous vehicle is saline.

6. A formulation according to claim 4, wherein the aqueous vehicle is WFI.

7. A formulation according to any one of claims 1 to 6, wherein the formulation also comprises a solubilizer.

8. A formulation according to claim 7, wherein the formulation comprises two or more solubilizers.

9. A formulation according to claim 7 or claim 8, wherein the or each solubilizer is a polyethoxylated fatty acid or a mixture thereof.

10. A formulation according to claim 1, wherein the formulation comprises:

from 30 % to 95% by volume DMA;

from 5% to 50% by volume aqueous vehicle; and

from 100 mg to 400 mg per mL protide.

11. A formulation according to claim 1, wherein the formulation comprises
from 30 % to 60% by volume DMA;
from 10% to 35% by volume a first solubilizer;
from 10% to 35% by volume a second solubilizer;
from 2% to 15% an aqueous vehicle; and
from 50 mg to 150 mg per mL protide.

12. A formulation according to claim 1, wherein the formulation comprises
from 0.1 % to 10% by volume DMA;
from 0.1 % to 10% by volume solubilizer or solubilizers;
from 85% to 99% by volume aqueous vehicle; and
from 2.0 mg to 12.0 mg per mL protide.

13. A formulation according to claim 12, wherein the formulation comprises:
from 1 % to 8% by volume DMA;
from 0.5 % to 4% by volume a first solubilizer;
from 0.5 % to 4% by volume a second solubilizer;
from 85% to 99% by volume aqueous vehicle; and
from 2.0 mg to 12.0 mg per mL protide.

14. A formulation according to any preceding claim wherein the protide is 5-fluoro-2'-deoxyuridine-5'-*O*-[1-naphthyl (benzoxy-L-alaninyl)] phosphate (NUC-3373).

15. A formulation according to any one of claims 1 to 13, wherein the protide is 3'-deoxyadenosine-5'-O-[phenyl(benzyloxy-L-alaninyl)] phosphate (NUC-7738).

16. A formulation according to any one of claims 1 to 13, wherein the protide is 2-chloro-2'-beta-fluoro-2'-deoxyadenosine-5'-[phenyl-(benzoxy-L-(alaninyl)]- phosphate (CPF-448).

17. A formulation according to any preceding claim for use in the treatment of cancer.

18. Use of a pharmaceutical formulation comprising:

a protide, wherein the protide is not gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate (NUC-1031);

a polar aprotic solvent; and

optionally one or more pharmaceutically acceptable excipients;

in the manufacture of a medicament for the treatment of cancer, wherein the medicament is to be administered to a subject in need thereof.

19. The use according to claim 18, wherein the medicament is to be administered in accordance with the following steps:

diluting a first solution comprising the protide and a polar aprotic solvent and optionally an aqueous vehicle with a second solution comprising a polar aprotic solvent and one or more solubilizers to form a third solution;

diluting the third solution with an aqueous vehicle to provide a fourth solution; and administering the fourth solution to the subject by infusion or injection.

20. The use according to claim 18, wherein the medicament is to be administered in accordance with the following steps:

flushing a Central Venous Administration Device (CVAD) with a first portion of a first solution, the first solution comprising a polar aprotic solvent and an aqueous vehicle;

administering a second formulation to the patient via the CVAD, the second formulation comprising the polar aprotic solvent, the aqueous vehicle and the protide; and

optionally flushing the CVAD with a second portion of the first formulation.

21. The use according to any of claims 18 to 20, wherein the polar aprotic solvent is DMA.

22. The use according to any of claims 18 to 21 , wherein the protide is 5-fluoro-2'-deoxyuridine- 5'-*O*-[1-naphthyl (benzoxy-L-alaninyl)] phosphate (NUC-3373).

23. The use according to any of claims 18 to 21, wherein the protide is 3'-deoxyadenosine- 5'-O-[phenyl(benzyloxy-L-alaninyl)] phosphate (NUC-7738).

24. The use according to any of claims 18 to 21, wherein the protide is 2-chloro-2'-beta-fluoro-2'-deoxyadenosine-5'-[phenyl-(benzoxy-L-(alaninyl)]-phosphate (CPF-448).

25. A kit, the kit comprising:

a first formulation comprising the polar aprotic and the protide and optionally an aqueous vehicle;

a second formulation comprising the polar aprotic solvent and one or more solubilizers;

wherein the protide is not gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate.

26. A kit, the kit comprising:

a first solution comprising a polar aprotic solvent and an aqueous vehicle; and

a second formulation comprising the polar aprotic solvent, the aqueous vehicle and the protide;

wherein the protide is not gemcitabine-[phenyl-benzoxy-L-alaninyl)]-phosphate (NUC-1031).

27. A kit of claim 25 or claim 26, wherein the polar aprotic solvent is DMA.

28. A kit of any of claims 25 to 27, wherein the protide is NUC-3373 5-fluoro-2'-deoxyuridine-5'-*O*-[1-naphthyl (benzoxy-L-alaninyl)] phosphate (NUC-3373).

29. A kit of any of claims 25 to 27, wherein the protide is 3'-deoxyadenosine-5'-O-[phenyl(benzyloxy-L-alaninyl)] phosphate (NUC-7738).

30. A kit of any of claims 25 to 27, wherein the protide is 2-chloro-2'-beta-fluoro-2'-deoxyadenosine-5'-[phenyl-(benzoxy-L-(alaninyl)]-phosphate (CPF-448).