CLAIMS

1. A pharmaceutical aqueous formulation comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a pharmaceutically acceptable organic or inorganic acid salt thereof, a pharmaceutically acceptable organic or inorganic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein sufficient of the pharmaceutically acceptable organic or inorganic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution, with the proviso that the organic or inorganic acid (including a salt thereof) is not a sulphonic acid.

2. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a pharmaceutically acceptable organic or inorganic acid salt thereof, a pharmaceutically acceptable organic or inorganic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of at least 6mg/ml and wherein sufficient of the pharmaceutically acceptable organic or inorganic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution, with the proviso that the organic or inorganic acid (including a salt thereof) is not a sulphonic acid.

3. A pharmaceutical aqueous formulation as claimed in claim 1 or 2 wherein the pharmaceutically acceptable organic or inorganic acid is selected from lactic acid, acetic acid, maleic acid, succinic acid, citric acid, malic acid, tartaric acid, hydrochloric acid and orthophosphoric acid.

4. A pharmaceutical aqueous formulation as claimed in claim 1 or 2 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-

(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a lactate salt thereof, lactic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 30mg/ml or from 6 to less than 35mg/ml and wherein sufficient lactic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

5. A pharmaceutical aqueous formulation as claimed in claim 4 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, lactic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 30mg/ml or from 6 to less than 35mg/ml and wherein sufficient lactic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

6. A pharmaceutical aqueous formulation as claimed in claim 4 comprising a lactate salt of 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, lactic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 30mg/ml or from 6 to less than 35mg/ml and wherein sufficient lactic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

7. A pharmaceutical aqueous formulation as claimed in claim 4 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a lactate salt thereof, lactic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin

and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 25, 6 to 20, 6 to 15, 10 to 30, 10 to 25, or 10 to 20mg/ml and wherein sufficient lactic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

8. A pharmaceutical aqueous formulation as claimed in claim 4 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, lactic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 25, 6 to 20, 6 to 15, 10 to 30, 10 to 25, or 10 to 20mg/ml and wherein sufficient lactic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

9. A pharmaceutical aqueous formulation as claimed in claim 4 comprising a lactate salt of 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, lactic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 25, 6 to 20, 6 to 15, 10 to 30, 10 to 25, or 10 to 20mg/ml and wherein sufficient lactic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

10. A pharmaceutical aqueous formulation as claimed in claim any one of claims 4 to 9 wherein the pharmaceutically acceptable beta- or gamma-cyclodextrin used is 2-hydroxypropyl-beta-cyclodextrin, sulphobutylether-β-cyclodextrin (SBECD) or gamma-cyclodextrin.

11. A pharmaceutical aqueous formulation as claimed in claim 10 wherein the pharmaceutically acceptable beta- or gamma-cyclodextrin used is 2-hydroxypropyl-beta-cyclodextrin or gamma-cyclodextrin.

12. A pharmaceutical aqueous formulation as claimed in claim 4 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a lactate salt thereof, lactic acid, sulphobutylether-β-cyclodextrin (SBECD) and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 25mg/ml or from 6 to less than 30mg/ml and wherein sufficient lactic acid and sulphobutylether-β-cyclodextrin (SBECD) are present to provide a clear solution.

13. A pharmaceutical aqueous formulation as claimed in claim 4 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a lactate salt thereof, lactic acid, 2-hydroxypropyl-beta-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 30mg/ml or from 6 to less than 35mg/ml and wherein sufficient lactic acid and 2-hydroxypropyl-beta-cyclodextrin are present to provide a clear solution.

14. A pharmaceutical aqueous formulation as claimed in claim 4 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a lactate salt thereof, lactic acid, 2-hydroxypropyl-beta-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 30, 6 to 25, 6 to 20, 6 to 15, 10 to 30, 10 to 25, or 10 to 20mg/ml and

wherein sufficient lactic acid and 2-hydroxypropyl-beta-cyclodextrin are present to provide a clear solution.

15. A pharmaceutical aqueous formulation as claimed in claim 4 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a lactate salt thereof, lactic acid, 2-hydroxypropyl-beta-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 6 to 30, 6 to 25, 6 to 20, 6 to 15, 10 to 30, 10 to 25, or 10 to 20mg/ml and wherein the lactic acid concentration is from 10 to 100, 15 to 100 or 30 to 100mM and the 2-hydroxypropyl-beta-cyclodextrin concentration is from 15 to 120, 20 to 120 or 35 to 120mg/ml to provide a clear solution.

16. A pharmaceutical aqueous formulation as claimed in claim 4 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, lactic acid, 2-hydroxypropyl-beta-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 10 to 30 or 10 to 20mg/ml and wherein the lactic acid concentration is from 20 to 100 or 30 to 100mM and the 2-hydroxypropyl-beta-cyclodextrin concentration is from 35 to 120mg/ml to provide a clear solution

17. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a acetate salt thereof, acetic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 3 to 15 mg/ml or from 3 to less than 20mg/ml and wherein sufficient acetic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

18. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a maleate salt thereof, maleic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 3 to 30mg/ml or from 3 to less than 35mg/ml and wherein sufficient maleic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

19. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a succinate salt thereof, succinic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 3 to 65mg/ml or from 3 to less than 70mg/ml and wherein sufficient succinic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

20. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a citrate salt thereof, citric acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 3 to 55mg/ml or from 3 to less than 60mg/ml and wherein sufficient citric acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

21. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a malate salt thereof, malic acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 3 to 65mg/ml or from 3 to less than 70mg/ml and wherein sufficient malic acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

22. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a tartrate salt thereof, tartaric acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 3 to 65mg/ml or from 3 to less than 70mg/ml and wherein sufficient tartaric acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

23. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a hydrochloride salt thereof, hydrochloric acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 3 to 60mg/ml or from 3 to less than 65mg/ml and wherein sufficient hydrochloric acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

24. A pharmaceutical aqueous formulation as claimed in claim 1 comprising 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea, or a phosphate salt thereof, orthophosphoric acid, a pharmaceutically acceptable beta- or gamma-cyclodextrin and water, wherein 1-(4-{[4-(dimethylamino)piperidin-1-yl]carbonyl}phenyl)-3-[4-(4,6-dimorpholin-4-yl-1,3,5-triazin-2-yl)phenyl]urea is present at a solution concentration of from 4 to 50mg/ml or from 4 to less than 55mg/ml and wherein sufficient orthophosphoric acid and pharmaceutically acceptable beta- or gamma-cyclodextrin are present to provide a clear solution.

25. A formulation as claimed in any one of claims 1 to 14 or 17 to 24 wherein from 10 to 200mM or from 50 to 200mM of the pharmaceutically acceptable organic or inorganic acid is used.

26. A formulation as claimed in any one of claims 1 to 14 or 17 to 25 wherein from 2 to 30% w/v, from 5 to 20% w/v or from 15 to 30% w/v of the cyclodextrin is used.

27. A lyophilised formulation obtainable by freeze drying a formulation as claimed in any one of claims 1 to 26.

28. A lyophilised formulation as claimed in claim 27 obtainable by freeze drying a formulation as claimed in any one of claims 1 to 26 optionally containing a bulking agent.

29. A lyophilised formulation as claimed in claim 28 wherein the bulking agent is mannitol.

30. A pharmaceutical aqueous solution formulation obtainable as a clear solution by reconstitution or constitution of a lyophilized formulation as claimed in any one of claims 27 to 29 using water or an aqueous solution comprising a tonicity modifier.

31. A pharmaceutical aqueous solution formulation as claimed in claim 30 wherein the tonicity modifier is dextrose, sucrose or mannitol, or is a mixture of any 2 or more thereof.

32. A pharmaceutical aqueous solution formulation as claimed in any one of claims 1 to 26, or 30 or 31, that is adjusted, as necessary, to have a pH suitable for intravenous or parenteral administration.

33. A formulation as claimed in any one of claims 1 to 32 for use as a medicament.

34. A formulation as claimed in any one of claims 1 to 32 for use in the treatment of cancer.

~~35. A method of treatment of cancer in a mammal comprising treatment of the mammal with an effective amount of a formulation as claimed in any one of claims 1 to 32.~~

35. Use of an effective amount of a formulation as claimed in any one of claims 1 to 32 in the manufacture of a medicament for the treatment of cancer in a mammal.