## CLAIMS

1. Use of an effective amount of gemcitabine in the manufacture of a medicament for the treatment of muscle invasive bladder cancer, wherein the medicament is to be provided as a maintenance therapy for an individual,
wherein the maintenance therapy follows at least one previous therapy,
wherein the maintenance therapy comprises gemcitabine to be continuously administered to the individual two or more times during two or more maintenance phase delivery periods,
wherein the gemcitabine is to be delivered locally to the bladder of the individual,
wherein each maintenance phase delivery period is at least one week,
wherein there is a rest period between each maintenance phase delivery period of at least one month.

2. The use of claim 1, wherein the gemcitabine is to be delivered into the bladder by an intravesicular device.

3. The use of claim 2, wherein the intravesicular device contains about 225 mg gemcitabine.

4. The use of any of claims 1-3, wherein the maintenance phase delivery periods are each 3 weeks.

5. The use of any of claims 1-4, wherein the rest period is about 3 months.

6. The use of any of claims 1-5, wherein the gemcitabine is to be delivered at a dose from 1 mg/day to 300 mg/day during the maintenance phase delivery periods.

7. The use any one of claims 1-6, wherein the concentration of gemcitabine in the urine is from 1 μg/mL to 10 μg/mL during the maintenance phase delivery periods.

8. The use of claim 7, wherein the concentration of gemcitabine in the urine is about 10 μg/mL during the maintenance phase delivery periods.

9. The use of any one of claims 1-8, wherein the individual is ineligible for or has refused cisplatin-based chemotherapy.

10. The use of any one of claims 1-9, wherein the individual is unfit for, ineligible for, or has refused a radical cystectomy.

11. The use of any one of claims 1-10 comprising 4 delivery periods, wherein the rest period between each delivery period is about 3 months.

12. The use of any one of claims 1-10, wherein the rest period between each delivery period is about 3 months, and wherein the gemcitabine is to be delivered into the bladder about every 3 months for the lifetime of the individual.

13. Use of an effective amount of gemcitabine in the manufacture of a medicament for the treatment of muscle invasive bladder cancer in an individual comprising

a) an effective amount of gemcitabine to be administered to the individual continuously during an induction phase; and

b) an effective amount of gemcitabine to be administered to the individual continuously during a maintenance phase,

wherein the gemcitabine is to be delivered locally to the bladder of the individual,

wherein the induction phase and maintenance phases are separated by a rest period, and

wherein the induction phase is about 12 weeks.

14. Use of an effective amount of gemcitabine in the manufacture of a medicament for the treatment of muscle invasive bladder cancer, wherein the medicament is for bladder preservation in an individual comprising

a) an effective amount of gemcitabine to be administered to the individual continuously during an induction phase; and

b) an effective amount of gemcitabine to be administered to the individual continuously during a maintenance phase,

wherein the gemcitabine is to be delivered locally to the bladder of the individual,

wherein the induction phase and maintenance phases are separated by a rest period,

wherein the induction phase is about 12 weeks.

15. The use of claim 13 or 14, wherein the gemcitabine is to be delivered into the bladder by an intravesicular device.

16. The use of claim 15, wherein the intravesicular device contains about 225 mg gemcitabine.

17. The use of any one of claims 13-16 wherein the rest period between the induction phase and the maintenance phase is about 3 months.

18. The use of any one of claims 13-16, wherein the maintenance phase comprises two or more maintenance phase gemcitabine delivery periods.

19. The use of claim 18, wherein the maintenance phase gemcitabine delivery periods are each separated by a rest period of about 3 months.

20. The use of claim 18 or 19, wherein the maintenance phase gemcitabine delivery periods are each 3 weeks.

21. The use of any of claims 18-20, wherein the gemcitabine is to be delivered at a dose from 1 mg/day to 300 mg/day during the induction phase or the maintenance phase delivery periods.

22. The use any one of claims 1-21, wherein the concentration of gemcitabine in the urine is from 1 μg/mL to 10 μg/mL during the induction phase or the maintenance phase delivery periods.

23. The use of any one of claims 13-22, wherein the individual is ineligible for or has refused cisplatin-based chemotherapy.

24. The use of any one of claims 13-23, wherein the individual is unfit for, ineligible for or has refused a radical cystectomy.

25. The use of claim 3 or 16, wherein the device delivers 100 mg to 225 mg of gemcitabine to the bladder over three weeks.

26. The use of any one of claims 13-25, wherein the maintenance phase continues for at least one year.

27. The use of any one of claims 1-12 or 18-26, wherein the average concentration of gemcitabine in the urine is 5 μg/mL to 20 μg/mL for one week during the two or more maintenance phase gemcitabine delivery periods.

28. The use of any one of claims 1-12, wherein the maintenance therapy continues for at least one year.