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 by an intravesical device,
wherein the intravesical device contains 100 mg to 225 mg gemcitabine,
wherein the gemcitabine is to be delivered at a dose from 1 mg/day to 200 mg/day during the maintenance phase delivery periods,
wherein each maintenance phase delivery period is at least one week, and
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~~2. The use of claim ~~2~~1, wherein the ~~intravesicular~~ intravesical device contains about 225 mg gemcitabine.

~~4~~3. The use of any of ~~claims 1-3~~ claim 1 or claim 2, wherein the maintenance phase delivery periods are each 3 weeks.

~~5~~4. The use of any of claims 1-~~4~~3, 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.~~

5. The use of any one of claims 1-4, wherein the gemcitabine is to be delivered at a dose from 1 mg/day to 50 mg/day during the maintenance phase delivery periods.

6. The use of any one of claims 1-5, wherein the gemcitabine is to be delivered at a dose from 5 mg/day to 10 mg/day during the maintenance phase delivery periods.

7. The use of any one of claims 1-6, wherein the concentration of gemcitabine in the urine is from 1 µg/mL to 30 µg/mL during the maintenance phase delivery periods.

~~7~~8. The use of any one of claims 1-~~6~~7, wherein the concentration of gemcitabine in the urine is from 1 µg/mL to 10 µg/mL during the maintenance phase delivery periods.

~~8~~9. The use of claim ~~7~~8, wherein the concentration of gemcitabine in the urine is about 10 μg/mL during the maintenance phase delivery periods.

~~9~~10. The use of any one of claims 1-~~8~~9, wherein the individual is ineligible for or has refused cisplatin-based chemotherapy.

~~10~~11. The use of any one of claims 1-~~9~~10, wherein the individual is unfit for, ineligible for, or has refused a radical cystectomy.

~~11~~12. The use of any one of claims 1-~~10~~11, comprising 4 delivery periods, wherein the rest period between each delivery period is about 3 months.

~~12~~13. The use of any one of claims 1-~~10~~12, 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.

14. The use of any one of claims 1-13, wherein the previous therapy comprises gemcitabine to be administered continuously and locally to the bladder of the individual.

15. The use of any one of claims 1-14, wherein the individual has T2, T3, or T4 bladder cancer.

16. The use of any one of claims 1-15, wherein the individual has cT2, or cT3 bladder cancer.

17. The use of any one of claims 1-16, wherein the individual has M0 or N0 bladder cancer.

18. The use of any one of claims 1-17, wherein the maintenance phase delivery periods are each 7 to 21 days.

19. The use of any one of claims 1-18, wherein the maintenance phase delivery periods are each 14 to 21 days.

~~13~~20. 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 one or more induction phase delivery periods during an induction phase; and

b) an effective amount of gemcitabine to be administered to the individual continuously during one or more maintenance phase delivery periods during a maintenance phase,

wherein the gemcitabine is to be delivered locally to the bladder of the individual by an intravesical device,

wherein the intravesical device contains 100 mg to 225 mg of gemcitabine,

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

wherein the induction phase is about 12 weeks, and

wherein the gemcitabine is to be delivered at a dose from 1 mg/day to 200 mg/day during the induction phase delivery periods or the maintenance phase delivery periods.

~~14~~21. 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 one or more induction phase delivery periods during an induction phase; and

b) an effective amount of gemcitabine to be administered to the individual continuously during one or more maintenance phase delivery periods during a maintenance phase,

wherein the gemcitabine is to be delivered locally to the bladder of the individual by an intravesical device,

wherein the intravesical device contains 100 mg to 225 mg of gemcitabine,

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

wherein the induction phase is about 12 weeks, and

wherein the gemcitabine is to be delivered at a dose from 1 mg/day to 200 mg/day during the induction phase delivery periods or the maintenance phase delivery periods.

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

~~16~~22. The use of claim ~~15~~20 or claim 21, wherein the ~~intravesicular~~ intravesical device contains about 225 mg gemcitabine.

~~17~~23. The use of any one of claims ~~13~~20-~~16~~22, wherein the rest period between the induction phase and the maintenance phase is about 3 months.

24. The use of any one of claims 20-22, wherein the rest period between the induction phase and the maintenance phase is at least one month.

25. The use of any one of claims 20-22, wherein the rest period between the induction phase and the maintenance phase is about six weeks.

~~18~~26. The use of any one of claims ~~13~~20-~~16~~25, wherein the maintenance phase comprises two or more maintenance phase gemcitabine delivery periods.

~~19~~27. The use of claim ~~18~~26, wherein the maintenance phase gemcitabine delivery periods are each separated by a rest period of about 3 months.

~~20~~28. The use of claim ~~18 or 19~~ 26 or 27, wherein the induction phase delivery periods or the maintenance phase ~~gemcitabine~~ delivery periods are each 3 weeks.

29. The use of any one of claims 20-27, wherein the induction phase delivery periods or the maintenance phase delivery periods are each about 2 weeks.

30. The use of any one of claims 20-29, wherein the gemcitabine is to be delivered at a dose from 1 mg/day to 50 mg/day during the induction phase delivery periods and/or the maintenance phase delivery periods.

31. The use of any one of claims 20-30, wherein the gemcitabine is to be delivered at a dose from 5 mg/day to 10 mg/day during the induction phase delivery periods and/or the maintenance phase delivery periods.

32. The use of any one of claims 20-31, wherein the concentration of gemcitabine in the urine is from 1 μg/mL to 30 μg/mL during the induction phase delivery periods and/or the maintenance phase delivery periods.

~~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~~33. The use any one of claims ~~1~~20-~~21~~32, wherein the concentration of gemcitabine in the urine is from 1 μg/mL to 10 μg/mL during the induction phase delivery periods and/or the maintenance phase delivery periods.

~~23~~34. The use of any one of claims ~~13~~20-~~22~~33, wherein the individual is ineligible for or has refused cisplatin-based chemotherapy.

~~24~~35. The use of any one of claims ~~13~~20-~~23~~34, 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~~36. The use of any one of claims ~~13~~20-~~25~~35, wherein the maintenance phase continues for at least one year.

37. The use of any one of claims 20-36, wherein the individual has T2, T3, or T4 bladder cancer.

38. The use of any one of claims 20-37, wherein the individual has cT2, or cT3 bladder cancer.

39. The use of any one of claims 20-38, wherein the individual has M0 or N0 bladder cancer.

40. The use of any one of claims 20-39, wherein the induction phase delivery periods and/or the maintenance phase delivery periods are each 7 to 21 days.

41. The use of any one of claims 20-40, wherein the induction phase delivery periods and/or the maintenance phase delivery periods are each 14 to 21 days.

42. The use of any one of claims 1-41, wherein the intravesical device delivers 100 mg to 225 mg of gemcitabine to the individual over a 3 week period.

43. The use of claim 42, wherein the intravesical device delivers about 200 mg of gemcitabine to the individual over a 3 week period.

~~27~~44. The use of any one of claims 1-~~12~~19 or ~~18~~26-~~26~~28, 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~~45. The use of any one of claims 1-~~12~~19, wherein the maintenance therapy continues for at least one year.