release gemcitabine into the bladder at a mean average amount of from 1 mg to about 300 mg per day of the gemcitabine. The gemcitabine contained in the housing may be in a non-liquid form. The housing may be elastically deformable between a retention shape configured to retain the device in a patient's bladder and a deployment shape for passage of the device through the patient's urethra. In an embodiment, the device is configured to release from 1 mg to 100 mg of gemcitabine per day for up to 7 days. In another embodiment, the device is configured to release from 20 mg to 300 mg of gemcitabine per day for up to 7 days.

In still another aspect, a method is provided of administering a drug to a patient in need of treatment of the prostate. The method includes locally administering gemcitabine into the bladder of a patient to achieve a sustained concentration of the gemcitabine in urine in the bladder sufficient to produce a therapeutic concentration of the gemcitabine in the prostate. In one embodiment, the method includes administering at least a second therapeutic agent to the patient. The second therapeutic agent may be administered intravesically. The second therapeutic agent may include a cytotoxic agent, an analgesic agent, an anti-inflammatory agent, or a combination thereof. The second therapeutic agent may prevent, treat, or ameliorate cystitis of the bladder.

In one aspect, there is provided the use of gemcitabine in the manufacture of a medicament for the treatment of ~~the~~ prostate cancer, wherein the medicament is to be locally administered into the bladder of a patient to achieve a sustained concentration of the medicament in the urine in the bladder sufficient to produce a therapeutic concentration of the medicament in the prostate, wherein the medicament is to be locally administered into the patient's bladder at a mean average amount of from 1 mg/day to ~~about~~ 300 mg/day of the gemcitabine.

In one aspect, there is provided the use of gemcitabine in the manufacture of a medicament for treatment of ~~the~~ prostate cancer in a patient in need thereof, wherein the medicament is to be locally administered into the bladder of the patient to achieve a sustained concentration of the gemcitabine in urine in the bladder sufficient to produce a therapeutic concentration of the gemcitabine in the prostate.

Brief Description of the Drawings

FIGS. 1A-1B illustrate one embodiment of an intravesical drug delivery device that may be used for administering gemcitabine as described herein.

What is claimed is:

1. Use of gemcitabine in the manufacture of a medicament for the treatment of the prostate, wherein the medicament is to be locally administered into the bladder of a patient to achieve a sustained concentration of the medicament in the urine in the bladder sufficient to produce a therapeutic concentration of the medicament in the prostate,

wherein the medicament is to be locally administered into the patient's bladder at a mean average amount of from 1 mg/day to about 300 mg/day of the gemcitabine.

2. The use of claim 1, wherein the medicament is to be locally administered into the patient's bladder continuously.

3. The use of claim 2, wherein the medicament is to be locally administered into the patient's bladder continuously over a period of at least 2 hours.

4. The use of claim 1, wherein the medicament is to be locally administered into the patient's bladder intermittently.

5. The use of claim 1, wherein the patient is in need of treatment for prostate cancer.

6. The use of claim 1, wherein the medicament is to be administered into the bladder from an intravesical drug delivery device which continuously releases the medicament into the urine in the bladder over a sustained period.

7. The use of claim 6, wherein the intravesical drug delivery device continuously releases the medicament into the urine in the bladder over a period of at least 2 hours.

8. The use of claim 6, wherein the intravesical drug delivery device continuously releases the medicament into the urine in the bladder over a period of 1 day to 14 days.

9. The use of claim 6, wherein the intravesical drug delivery device comprises a housing which contains and controllably releases the medicament and is elastically deformable between a retention shape configured to retain the device in a patient's bladder and a deployment shape for passage of the device through the patient's urethra.

10. The use of claim 9, wherein the medicament contained in the housing is in a non-liquid form.

11. The use of claim 10, wherein the non-liquid form is selected from the group consisting of tablets, granules, semisolids, capsules, and combinations thereof.

12. The use of claim 1, wherein the medicament is to be delivered into the bladder from a coating substance applied to the bladder, which coating substance releases the medicament into the urine in the bladder over a sustained period.

13. The use of claim 12, wherein the coating substance comprises a mucoadhesive formulation.

14. The use of claim 1, wherein the locally administered comprises pumping a liquid form of the medicament into the bladder through a urethral catheter which is deployed into the bladder.

15. The use of any one of claims 1 to 14, wherein the medicament is to be locally administered into the patient's bladder from 1 mg/day to 100 mg/day of the gemcitabine for up to 7 days.

16. The use of any one of claims 1 to 14, wherein the medicament is to be locally administered into the patient's bladder from 20 mg/day to 300 mg/day of the gemcitabine for up to 7 days.

17. A drug delivery device comprising a medicament according to any one of the preceding claims, configured to release the gemcitabine when the drug delivery device is inserted into the bladder.

18. Use of gemcitabine in the manufacture of a medicament for treatment of the prostate in a patient in need thereof, wherein the medicament is to be locally administered into the bladder of the patient to achieve a sustained concentration of the gemcitabine in urine in the bladder sufficient to produce a therapeutic concentration of the gemcitabine in the prostate.

19. The use of claim 18, wherein at least a second therapeutic agent is to be administered to the patient.

20. The use of claim 19, wherein the second therapeutic agent is administered intravesically.

21. The use of claim 19 or 20, wherein the second therapeutic agent comprises a cytotoxic agent, an analgesic agent, an anti-inflammatory agent, or a combination thereof.

22. A medical device comprising:

a housing configured for intravesical insertion; and

a dosage form comprising gemcitabine,

wherein the housing holds the dosage form and is configured to release the gemcitabine into the bladder in an amount therapeutically effective for the treatment of the prostate, wherein the device is configured to release gemcitabine into the bladder at a mean average amount of from 1 mg/day to about 300 mg/day of the gemcitabine.

23. The device of claim 22, wherein the gemcitabine contained in the housing is in a non-liquid form.

24. The device of claim 22, wherein the housing is elastically deformable between a retention shape configured to retain the device in a patient's bladder and a deployment shape for passage of the device through the patient's urethra.

25. The device of any one of claims 22 to 24, which is configured to release from 1 mg/day to 100 mg/day of the gemcitabine for up to 7 days.

26. The device of any one of claims 22 to 24, which is configured to release from 20 mg/day to 300 mg/day of the gemcitabine for up to 7 days.

What is claimed is:

1. Use of gemcitabine in the manufacture of a medicament for the treatment of prostate cancer, wherein the medicament is to be locally administered into the bladder of a patient to achieve a sustained concentration of the medicament in the urine in the bladder sufficient to produce a therapeutic concentration of the medicament in the prostate,

wherein the medicament is to be locally administered into the patient's bladder at a mean average amount of from 1 mg/day to 300 mg/day of the gemcitabine.

2. The use of claim 1, wherein the medicament is to be locally administered into the patient's bladder continuously.

3. The use of claim 2, wherein the medicament is to be locally administered into the patient's bladder continuously over a period of at least 2 hours.

4. The use of claim 1, wherein the medicament is to be locally administered into the patient's bladder intermittently.

5. The use of claim 1, wherein the medicament is to be administered into the bladder from an intravesical drug delivery device which continuously releases the medicament into the urine in the bladder over a sustained period.

6. The use of claim 5, wherein the intravesical drug delivery device continuously releases the medicament into the urine in the bladder over a period of at least 2 hours.

7. The use of claim 5, wherein the intravesical drug delivery device continuously releases the medicament into the urine in the bladder over a period of 1 day to 14 days.

8. The use of claim 5, wherein the intravesical drug delivery device comprises a housing which contains and controllably releases the medicament and is elastically deformable between a retention shape configured to retain the device in a patient's bladder and a deployment shape for passage of the device through the patient's urethra.

9. The use of claim 8, wherein the medicament contained in the housing is in a non-liquid form.

10. The use of claim 9, wherein the non-liquid form is selected from the group consisting of tablets, granules, semisolids, capsules, and combinations thereof.

11. The use of claim 1, wherein the medicament is to be delivered into the bladder from a coating substance applied to the bladder, which coating substance releases the medicament into the urine in the bladder over a sustained period.

12. The use of claim 11, wherein the coating substance comprises a mucoadhesive formulation.

13. The use of claim 1, wherein the locally administered comprises pumping a liquid form of the medicament into the bladder through a urethral catheter which is deployed into the bladder.

14. The use of any one of claims 1 to 13, wherein the medicament is to be locally administered into the patient's bladder from 1 mg/day to 100 mg/day of the gemcitabine for up to 7 days.

15. The use of any one of claims 1 to 13, wherein the medicament is to be locally administered into the patient's bladder from 20 mg/day to 300 mg/day of the gemcitabine for up to 7 days.

16. A drug delivery device comprising a medicament according to any one of the preceding claims, configured to release the gemcitabine when the drug delivery device is inserted into the bladder.

17. Use of gemcitabine in the manufacture of a medicament for treatment of prostate cancer in a patient in need thereof, wherein the medicament is to be locally administered into the bladder of the patient to achieve a sustained concentration of the gemcitabine in urine in the bladder sufficient to produce a therapeutic concentration of the gemcitabine in the prostate.

18. The use of claim 17, wherein at least a second therapeutic agent is to be administered to the patient.

19. The use of claim 18, wherein the second therapeutic agent is administered intravesically.

20. The use of claim 18 or 19, wherein the second therapeutic agent comprises a cytotoxic agent, an analgesic agent, an anti-inflammatory agent, or a combination thereof.

21. A medical device comprising:

a housing configured for intravesical insertion; and

a dosage form comprising gemcitabine,

wherein the housing holds the dosage form and is configured to release the gemcitabine into the bladder in an amount therapeutically effective for the treatment of prostate cancer, wherein the device is configured to release gemcitabine into the bladder at a mean average amount of from 1 mg/day to 300 mg/day of the gemcitabine.

22. The device of claim 21, wherein the gemcitabine contained in the housing is in a non-liquid form.

23. The device of claim 21, wherein the housing is elastically deformable between a retention shape configured to retain the device in a patient's bladder and a deployment shape for passage of the device through the patient's urethra.

24. The device of any one of claims 21 to 23, which is configured to release from 1 mg/day to 100 mg/day of the gemcitabine for up to 7 days.

25. The device of any one of claims 21 to 23, which is configured to release from 20 mg/day to 300 mg/day of the gemcitabine for up to 7 days.