In one aspect of the present disclosure, there is provided a use of gemcitabine in the manufacture of a medicament for the treatment of bladder cancer in a patient, wherein the medicament is to be locally administered into the bladder of the patient, before and/or after transurethral resection of bladder tumor (TURBT), to achieve a sustained concentration of the gemcitabine in the urine in the bladder sufficient to produce a therapeutic concentration of the gemcitabine in the bladder tissues, wherein the locally administering into the patient's bladder at a mean average amount of from 1 mg/day to 300 mg/day of the gemcitabine free base equivalent (FBE) continuously over a period of from 1 day to 30 days,
wherein the gemcitabine is to be delivered into the bladder from an intravesical drug delivery device which releases the gemcitabine into the urine in the bladder over the period.

In embodiments, the local administer into the patient's bladder is at a mean average amount of from 1 mg/day to 200 mg/day of the gemcitabine (FBE), from 5 mg/day to 100 mg/day of

The present disclosure also provides methods of treating bladder cancer are provide by locally administering the gemcitabine into the bladder of a patient to achieve a sustained concentration of the gemcitabine in the urine in the bladder sufficient to produce a therapeutic concentration of the gemcitabine in the bladder tissues. In embodiments, the

We claim:

1. Use of gemcitabine in the manufacture of a medicament for the treatment of bladder cancer in a patient, wherein the medicament is to be locally administered into the bladder of the patient, before and/or after transurethral resection of bladder tumor (TURBT), to achieve a sustained concentration of the gemcitabine in the urine in the bladder sufficient to produce a therapeutic concentration of the gemcitabine in the bladder tissues, wherein the locally administering into the patient's bladder is at a mean average amount of from 1 mg/day to 300 mg/day of the gemcitabine free base equivalent (FBE) continuously over a period of from 1 day to 30 days,
wherein the gemcitabine is to be delivered into the bladder from an intravesical drug delivery device which releases the gemcitabine into the urine in the bladder over the period.

2. The use of claim 1, wherein the locally administering into the patient's bladder is at a mean average amount of from 1 mg/day to 200 mg/day of the gemcitabine (FBE).

3. The use of claim 1, wherein the locally administering into the patient's bladder is at a mean average amount of from 5 mg/day to 100 mg/day of the gemcitabine (FBE).

4. The use of claim 1, wherein the locally administering into the patient's bladder is at a mean average amount of from 10 mg/day to 50 mg/day of the gemcitabine (FBE).

5. The use of claim 1, wherein the locally administering into the patient's bladder is at a mean average amount of from 15 mg/day to 25 mg/day of the gemcitabine (FBE).

6. The use of claim 1, wherein the locally administering into the patient's bladder is at a mean average amount of 20 mg/day of the gemcitabine (FBE).

7. The use of any one of claims 1 to 6, wherein the locally administering into the patient’s bladder is continuous over a period from 1 day to 14 days.

8. The use of any one of claims 1 to 6, wherein the locally administering into the patient’s bladder is continuous over a period from 1 day to 7 days.

9. The use of claim 1, wherein the intravesical drug delivery device comprises a housing which contains and controllably releases the gemcitabine 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 gemcitabine 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. A drug delivery device comprising a medicament according to any one of claims 1 to 11, configured to release the gemcitabine when the drug delivery device is inserted into the bladder.

13. The use of claim 1, wherein the intravesical drug delivery device comprises a housing which comprises a drug reservoir and a release orifice in communication with the drug reservoir, wherein the gemcitabine is contained in the drug reservoir with (i) a viscosity enhancing agent, (ii) an osmotic agent, or (iii) a combination of a viscosity enhancing agent and an osmotic agent.

14. The use of any one of claims 1 to 13, for the treatment of non-muscular invasive bladder cancer (NMIBC).

15. The use of claim 14, for the treatment of BCG refractory NMIBC.