the gemcitabine (FBE), from 10 mg/day to 50 mg/day of the gemcitabine (FBE), or from 15 mg/day to 25 mg/day of the gemcitabine (FBE). In one case, the locally administering into the patient's bladder is at a mean average amount of about 20 mg/day of the gemcitabine (FBE). The local administer into the patient's bladder may be continuous or intermittent. In embodiments, the continuous or intermittent administration is over a period from 1 day to 30 days, from 1 day to 14 days, or from 1 day to 7 days.

In a preferred embodiment, the gemcitabine is delivered into the bladder from an intravesical drug delivery device which continuously releases the gemcitabine into the urine in the bladder over a sustained period. In another embodiment, the gemcitabine is delivered into the bladder from a coating substance applied to the bladder, which coating substance (e.g., a mucoadhesive formulation) releases the gemcitabine into the urine in the bladder over a sustained period. In still another embodiment, a liquid form of the gemcitabine is pumped into the bladder over a sustained period through a urethral or suprapubic catheter which is deployed into the bladder.

The present disclosure also provides a drug delivery device for administering gemcitabine to a patient in need of treatment of bladder cancer by intravesically administering gemcitabine into the bladder of the patient to achieve a sustained concentration of the gemcitabine in urine in the bladder sufficient to produce a therapeutically effective concentration of the gemcitabine in the tissues of the bladder.

In a particular embodiment, the drug delivery device includes 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. In a preferred embodiment, the housing releases the gemcitabine without a predefined release aperture. In a particular version of this preferred embodiment, the housing releases the gemcitabine by diffusion through a drug permeable polymeric wall. The housing which contains and controllably releases the gemcitabine 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.

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. 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.

13. The use of any one of claims 1 to 12, wherein the bladder cancer is non-muscular invasive bladder cancer (NMIBC).

14. The use of claim 13, wherein the bladder cancer is BCG refractory NMIBC.