[0005] The disclosures of all publications, patents, patent applications and published patent applications referred to herein are hereby incorporated herein by reference in their entirety.

SUMMARY

[0006] The present application provides methods, compositions (including pharmaceutical compositions) and kits for treating bladder cancer in an individual comprising intravesical administration of an oncolytic virus, *e.g.*, CG0070.

[0007] In one example, provided herein is a method of treating bladder cancer in an individual, comprising intravesically administering to the individual an effective amount of an oncolytic virus once per week for three weeks during a maintenance phase, wherein the oncolytic virus comprises a viral vector comprising a tumor cell-specific promoter operably linked to a viral gene essential for replication of the oncolytic virus, and a heterologous gene encoding an immune-related molecule. In one aspect, the present disclosure refers to use of an effective amount of an oncolytic virus in the manufacture of a medicament for treating bladder cancer in an individual, wherein the individual has Ta or T1 stage bladder cancer and does not have carcinoma in situ (CIS), wherein the individual is unresponsive to BCG treatment, wherein the medicament is formulated for intravesical administration to the individual once per week for six weeks during a maintenance phase, wherein the medicament is to be administered to the individual once per week for six weeks during an induction phase prior to the maintenance phase, wherein the start of the induction phase and the start of the maintenance phase are separated by 6 months, wherein the oncolytic virus is CG0070, and wherein the oncolytic virus is to be administered at a dose of 1×10^{12} viral particles in both the induction phase and the maintenance phase.

[0008] In another example, provided herein is a method of bladder preservation in an individual comprising intravesically administering to the individual an effective amount of an oncolytic virus once per week for three weeks during a maintenance phase, wherein the oncolytic virus comprises a viral vector comprising a tumor cell-specific promoter operably linked to a viral gene essential for replication of the oncolytic virus, and a heterologous gene encoding an immune-related molecule. In one aspect, the present disclosure refers to use of an effective amount of an oncolytic virus in the manufacture of a medicament for bladder preservation in an individual having bladder cancer, wherein the individual has Ta or T1 stage bladder cancer and does not have carcinoma in situ, wherein the individual is unresponsive to BCG treatment, wherein the medicament is formulated for intravesical administration to the individual once per week for six weeks during a maintenance phase, wherein the medicament is to be administered to the individual once per week for six weeks during an induction phase prior to the maintenance phase, wherein the start of the induction phase and the start of the maintenance phase are separated by 6 months, wherein the oncolytic virus is CG0070, and wherein the oncolytic virus is to be administered at a dose of 1×10^{12} viral particles in both the induction phase and the maintenance phase.

[0009] In some examples, according to any of the methods described above, the oncolytic virus is administered once per week for three weeks every six months during the maintenance phase. In some examples, the method further comprises an induction phase prior to the maintenance phase, wherein the induction phase comprises administering to the induvial an effective amount of oncolytic virus once per week for six weeks. In some examples, the start of the induction phase and the start of the maintenance phase are separated by about 3 months. In some examples, the start of the induction phase and the start of the maintenance phase are separated by about 6 months. In some examples, the induction phase comprises administering to the individual an effective amount of an oncolytic virus once per week for six weeks on month zero and month three of a treatment regimen.

[0010] Also provided herein is a method of treating Ta or T1 bladder cancer in an individual who has not received a transurothelial resection of bladder tumor (TURBT), comprising intravesically administering to the individual an effective amount of an oncolytic virus, wherein the oncolytic virus comprises a viral vector comprising a tumor cell-specific promoter operably

CLAIMS

What is claimed is:

1. Use of an effective amount of an oncolytic virus in the manufacture of a medicament for treating bladder cancer in an individual, wherein the individual has Ta or T1 stage bladder cancer and does not have carcinoma in situ (CIS), wherein the individual is unresponsive to BCG treatment, wherein the medicament is formulated for intravesical administration to the individual once per week for six weeks during a maintenance phase, wherein the medicament is to be administered to the individual once per week for six weeks during an induction phase prior to the maintenance phase, wherein the start of the induction phase and the start of the maintenance phase are separated by 6 months, wherein the oncolytic virus is CG0070, and wherein the oncolytic virus is to be administered at a dose of 1×10^{12} viral particles in both the induction phase and the maintenance phase.

2. Use of an effective amount of an oncolytic virus in the manufacture of a medicament for bladder preservation in an individual having bladder cancer, wherein the individual has Ta or T1 stage bladder cancer and does not have carcinoma in situ, wherein the individual is unresponsive to BCG treatment, wherein the medicament is formulated for intravesical administration to the individual once per week for six weeks during a maintenance phase, wherein the medicament is to be administered to the individual once per week for six weeks during an induction phase prior to the maintenance phase, wherein the start of the induction phase and the start of the maintenance phase are separated by 6 months, wherein the oncolytic virus is CG0070, and wherein the oncolytic virus is to be administered at a dose of 1×10^{12} viral particles in both the induction phase and the maintenance phase.

3. The use of claim 1 or 2, wherein the individual has disease reoccurrence subsequent to BCG treatment.

4. The use of any one of claims 1-3, wherein the individual has failed the BCG treatment within 6 months.

5. The use of any one of claims 1-4, wherein the individual has not received a cystectomy.

6. The use of any one of claims 1-5, wherein the individual has refused or is ineligible for a cystectomy.

7. The use of any one of claims 1-6, wherein the oncolytic virus is to be administered in a volume of 50 mL.

8. The use of any one of claims 1-7, wherein the individual is to be further administered N-Dodecyl-β-D-maltoside (DDM) prior to the administration of the oncolytic virus.

9. The use of any one of claims 1-8, wherein:

(i) the oncolytic virus is not to be administered in conjunction with an immune checkpoint modulator; and/or

(ii) the oncolytic virus is to be administered as a single therapeutic agent.