CLAIMS

1. Use of an antibody or an antigen-binding fragment thereof, which specifically binds to a VP1 protein of a polyomavirus in the manufacture of a medicament for the treatment of a BK or JC polyomavirus infection in a human subject in need thereof, wherein

(a) the antibody or antigen binding fragment is to be parenterally administered to the subject;

(b) serum or tissue concentration of the antibody, or antigen-binding fragment thereof, in the subject is measured; and

(c) a further dosage of the antibody, or antigen-binding fragment thereof, is to be administered before the serum or tissue trough concentration (C_{trough}) in the subject falls below about 860 µg/mL;

wherein the dosing regimen maintains the serum or tissue concentration of the antibody, or antigen-binding fragment thereof, above the C_{trough} throughout the treatment,

(i) wherein the polyomavirus infection comprises a BK virus genotype I and wherein:

the renal tissue concentration at the C_{trough} is at least 2618-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof; or

the bladder tissue concentration at the C_{trough} is at least 500-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof,

wherein the EC_{50} is about 0.009 ± 0.010 µg/mL, or

(ii) wherein the polyomavirus infection comprises a BK virus genotype II and wherein:

the renal tissue concentration at C_{trough} ia at least 589-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof; or

the bladder tissue concentration at C_{trough} is at least 100-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof,

wherein the EC_{50} is about 0.040 ± 0.025 µg/mL, or

(iii) wherein the polyomavirus infection comprises a BK virus genotype III and wherein:

the renal tissue concentration at the C_{trough} is at least 253-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof; or

the bladder tissue concentration at the C_{trough} is at least 50-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof,

wherein the EC_{50} is about 0.093 ± 0.057 µg/mL, or

(iv) wherein the polyomavirus infection comprises a BK virus genotype IV and wherein:

the renal tissue concentration at the C_{trough} is at least 1122-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof; or

the bladder tissue concentration at the C_{trough} is at least 100-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof,

wherein the EC_{50} is about 0.021 ± 0.020 µg/mL, or

(v) wherein the polyomavirus infection comprises a JC virus and the tissue concentration at the C_{trough} is at least 29-fold above the EC_{50} of the antibody, or antigen-binding fragment thereof, wherein the EC_{50} is about 0.215 ± 0.130 µg/mL.

2. The use according to claim 1, wherein:

(i) the C_{trough} in (c) is for plasma, and the further dosage is to be administered before the plasma C_{trough} falls below about 860 µg/mL;

(ii) the C_{trough} in (c) is for renal tissue, and the further dosage is to be administered before the C_{trough} in renal tissue falls below about 120 µg/mL; or

(iii) the C_{trough} in (c) is for bladder tissue, and the further dosage is to be administered before the C_{trough} in bladder tissue falls below about 10 µg/mL.

3. The use according to claim 1 or 2, wherein the antibody or antigen-binding fragment thereof comprises

a heavy chain variable (V_H) region that comprises complementary determining region (CDR) V_HCDR1, V_HCDR2, and V_HCDR3 sequences of SEQ ID NOs: 6-8, respectively; and

a light chain variable (V_L) region that comprises V_LCDR1, V_LCDR2, and V_LCDR3 sequences of SEQ ID NOs: 9-11, respectively,

and variants thereof which specifically bind to the VP1 protein; optionally

wherein the V_H region comprises a sequence at least 80, 85, 90, 95, 97, 98, 99, or 100% identical to SEQ ID NO: 12, optionally wherein the V_H sequence has 1, 2, 3, 4, 5, or 6 alterations in the framework regions, optionally selected from one or more of V5Q, G9P, T10G, N30S, N30K, and N30Q; and

the V_L region comprises sequence at least 80, 85, 90, 95, 97, 98, 99, or 100% identical to SEQ ID NO: 13, optionally wherein the V_L sequence has 1, 2, 3, 4, 5, or 6 alterations in the framework regions, optionally

wherein the V_H region comprises, consists, or consists essentially of SEQ ID NO: 12 and the V_L region comprises, consists, or consists essentially of SEQ ID NO: 13.

4. The use according to any one of claims 1-3, wherein the dosing regimen comprises identifying the BK virus genotype or the JC virus in subject, optionally

wherein the polyomavirus infection comprises a BK virus selected from one or more of genotype I, II, III, and IV, or wherein the polyomavirus infection comprises a JC virus.

5. The use according to any one of claims 1-4, wherein the subject is immuno-compromised.

6. The use according to any one of claims 1-5, wherein the subject is about to undergo, is undergoing, or has undergone a transplant procedure, optionally an organ transplant or cell-based transplant procedure, optionally

wherein the transplant procedure is selected from a kidney transplant and a hematopoietic cell transplant (HCT).

7. The use according to any one of claims 1-6, wherein the subject has or is at risk for having a condition selected from BK virus-associated nephropathy, BK virus-associated hemorrhagic cystitis, and JC virus-associated progressive multifocal leukoencephalopathy.

8. The use according to any one of claims 1-7, wherein the dosage in (a) is about 1 to about 100 mg/kg, or about 10-30 mg/kg, or about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 60, 70, 80, 90, or 100 mg/kg, optionally wherein the dosage is to be administered intravenously or subcutaneously.

9. The use according to any one of claims 1-8, wherein the further dosage in (c) is the same as or different than the dosage in (a), optionally about 1 to about 100 mg/kg, or about 10-30 mg/kg, or about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 60, 70, 80, 90, or 100 mg/kg, optionally wherein the dosage is administered intravenously or subcutaneously.

10. The use according to any one of claims 1-9, wherein time between (a) and (c) is about, at least about, or no more than about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30 days, or 1, 2, 3, 4, 5, 6, 7, or 8 weeks, or 1, 2, or 3 months, optionally

comprising (b) measuring the serum or tissue levels in the subject about once every 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30 days, or about 1-3 times every 1, 2, 3, 4, 5, 6, 7, or 8 weeks, or about 1-6 times every 1, 2, or 3 months, optionally

wherein the time between (a) and (c) is about, at least about, or no more than about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30 days, or 1, 2, 3, 4, 5, 6, 7, or 8 weeks, or 1, 2, or 3 months.

11. The use according to any one of claims 1-10, wherein at least 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20% or more of the serum, circulating concentration of the antibody, or antigen-binding fragment thereof, penetrates an infected organ, optionally

wherein the infected organ is a bladder or a kidney or the central nervous system (CNS).

12. The use according to any one of claims 1-11, wherein the mean clearance of the antibody, or antigen binding fragment thereof, is about 0.0760-0.0996 mL/day/kg.

13. The use according to any one of claims 1-12, wherein the mean volume of distribution of the antibody, or antigen binding fragment thereof, is about 49.8-81.9 mL/kg.

14. The use according to any one of claims 1-13, which reduces BK or JC viremia and/or viruria in the subject, optionally by about or at least about 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%, 200%, 300%, 400%, 500%, 1000%, 2000%, 3000%, 4000%, or 5000% or more, relative to a control or prior to treatment with the antibody, or antigen-binding fragment thereof.

15. The use according to any one of claims 1-14, which reduces or improves one or more BK or JC virus-related symptoms in the subject, optionally one or more symptoms selected from blurred vision or other vision changes, brown or red urine, pain while urinating, reduced kidney function, difficulty urinating, cough, colds, trouble breathing, fever, muscle pain, muscle weakness, and/or seizures, optionally narrowed ureters, or kidney inflammation such as interstitial nephritis, optionally

16. The use according to any one of claims 1-15, wherein the antibody, or antigen-binding fragment thereof, is to be administered in a pharmaceutical composition that comprises histidine, a saccharide optionally sucrose, and a polyol optionally a polysorbate.