

## CLAIMS

1. An anti-BK virus antibody molecule or an anti-BK virus binding fragment thereof comprising:
- 5 a heavy chain variable region (VH) comprising a heavy chain complementarity determining region 1 (VHCDR1) amino acid sequence of SEQ ID NO: 21 or a sequence having one or two amino acid substitutions, a heavy chain complementarity determining region 2 (VHCDR2) amino acid sequence of SEQ ID NO: 22 or a sequence having one or two amino acid substitutions, and a heavy chain complementarity determining region 3 (VHCDR3) amino acid sequence of SEQ ID NO: 23 or a sequence having one or two amino acid substitutions; and
- 10 a light chain variable region (VL) comprising a light chain complementarity determining region 1 (VLCDR1) amino acid sequence of SEQ ID NO: 24 or a sequence having one or two amino acid substitutions, a light chain complementarity determining region 2 (VLCDR2) amino acid sequence of SEQ ID NO: 25 or a sequence having one or two amino acid substitutions, and a light chain complementarity determining region 3 (VLCDR3) amino acid sequence of SEQ ID NO: 26 or a sequence having one or two amino acid substitutions.
- 20 2. The antibody molecule or binding fragment thereof of claim 1, comprising:
- a heavy chain variable region (VH) comprising a heavy chain complementarity determining region 1 (VHCDR1) amino acid sequence of SEQ ID NO: 21, a heavy chain complementarity determining region 2 (VHCDR2) amino acid sequence of SEQ ID NO: 22, and a heavy chain complementarity determining region 3 (VHCDR3) amino acid sequence of SEQ ID NO: 23; and
- 25 a light chain variable region (VL) comprising a light chain complementarity determining region 1 (VLCDR1) amino acid sequence of SEQ ID NO: 24, a light chain complementarity determining region 2 (VLCDR2) amino acid sequence of SEQ ID NO: 25, and a light chain complementarity determining region 3 (VLCDR3) amino acid sequence of SEQ ID NO: 26.
- 30 3. The antibody molecule or binding fragment thereof of claims 1 or 2, comprising
- (i) a heavy chain variable region (VH) comprising the amino acid sequence of SEQ ID NO: 27, or an amino acid sequence having at least about 85%, 90%, 95%, or 99% sequence identity to SEQ ID NO: 27, and a light chain variable region (VL) comprising the amino acid sequence of SEQ ID NO: 28, or an amino acid sequence having at least about 85%, 90%, 95%, or 99% sequence identity to SEQ ID NO: 28; or
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- (ii) a heavy chain variable region (VH) comprising the amino acid sequence of SEQ ID NO: 27, or an amino acid sequence having at least about 85%, 90%, 95%, or 99% sequence identity to SEQ ID NO: 27, and a light chain variable region (VL) comprising the amino acid sequence of SEQ ID NO: 31, or an amino acid sequence having at least about 85%, 90%, 95%, or 99% sequence identity to SEQ ID NO: 31.

4. The antibody molecule or binding fragment thereof of any one of claims 1-3, comprising

- (i) a heavy chain variable region (VH) comprising the amino acid sequence of SEQ ID NO: 27, and a light chain variable region (VL) comprising the amino acid sequence of SEQ ID NO: 28; or

(ii) a heavy chain variable region (VH) comprising the amino acid sequence of SEQ ID NO: 27, and a light chain variable region (VL) comprising the amino acid sequence of SEQ ID NO: 31.

5. The antibody molecule or binding fragment thereof of any one of claims 1-4, comprising one or more one or more (e.g., 2, 3, 4, 5, 6, 7, 8 or 9) of the following properties:

- (i) binds to BK virus serotype I VP1 with a EC50 of less than about 10 nM, 1 nM, 0.9 nM, 0.8 nM, 0.7 nM, 0.6 nM, 0.5 nM, 0.4 nM, 0.3 nM, 0.2 nM, 0.19 nM, 0.18 nM, 0.17 nM, 0.16 nM, 0.15 nM, 0.14 nM, 0.13 nM, 0.12 nM, 0.11 nM, 0.10 nM, 0.09 nM, 0.08 nM, 0.07 nM, 0.06 nM, 0.05 nM, 0.04 nM, 0.03 nM or 0.02 nM e.g., when the antibody molecule or binding fragment thereof is tested as a bivalent molecule using ELISA, e.g., as described in Example 2;

- (ii) binds to BK virus serotype II VP1 with a EC50 of less than about 10 nM, 1 nM, 0.9 nM, 0.8 nM, 0.7 nM, 0.6 nM, 0.5 nM, 0.4 nM, 0.3 nM, 0.2 nM, 0.19 nM, 0.18 nM, 0.17 nM, 0.16 nM, 0.15 nM, 0.14 nM, 0.13 nM, 0.12 nM, 0.11 nM, 0.10 nM, 0.09 nM, 0.08 nM, 0.07 nM, 0.06 nM, 0.05 nM, 0.04 nM, 0.03 nM or 0.02 nM e.g., when the antibody molecule or binding fragment thereof is tested as a bivalent molecule using ELISA, e.g., as described in Example 2;

- (iii) binds to BK virus serotype III VP1 with a EC50 of less than about 10 nM, 1 nM, 0.9 nM, 0.8 nM, 0.7 nM, 0.6 nM, 0.5 nM, 0.4 nM, 0.3 nM, 0.2 nM, 0.19 nM, 0.18 nM, 0.17 nM, 0.16 nM, 0.15 nM, 0.14 nM, 0.13 nM, 0.12 nM, 0.11 nM, 0.10 nM, 0.09 nM, 0.08 nM, 0.07 nM, 0.06 nM, 0.05 nM, 0.04 nM, 0.03 nM or 0.02 nM e.g., when the antibody molecule or binding fragment thereof is tested as a bivalent molecule using ELISA, e.g., as described in Example 2;

- (iv) binds to BK virus serotype IV VP1 with a EC50 of less than about 10 nM, 1 nM, 0.9 nM, 0.8 nM, 0.7 nM, 0.6 nM, 0.5 nM, 0.4 nM, 0.3 nM, 0.2 nM, 0.19 nM, 0.18 nM, 0.17 nM, 0.16 nM, 0.15 nM, 0.14 nM, 0.13 nM, 0.12 nM, 0.11 nM, 0.10 nM, 0.09 nM, 0.08 nM, 0.07 nM, 0.06 nM, 0.05 nM, 0.04 nM, 0.03 nM or 0.02 nM e.g., when

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the antibody molecule or binding fragment thereof is tested as a bivalent molecule using ELISA, e.g., as described in Example 2;

- (v) does not bind to JC virus VP1;
- (vi) neutralizes BK virus serotype I;
- 5 (vii) neutralizes BK virus serotype II;
- (viii) neutralizes BK virus serotype III;
- (ix) neutralizes BK virus serotype IV.

6. An antibody molecule or a binding fragment thereof that competes for  
10 binding to BK virus serotype I VP1, BK virus serotype II VP1, BK virus serotype III VP1, and/or BK virus serotype IV VP1 with the antibody molecule or binding fragment thereof of any one of claims 1-5.

7. A pharmaceutical composition comprising the antibody molecule or binding  
15 fragment thereof of any one of claims 1-6 and a pharmaceutically acceptable carrier, excipient or stabilizer.

8. An antibody molecule or binding fragment thereof according to any one of  
20 claims 1-6 or a pharmaceutical composition according to claim 7 for use in the treatment or prevention of a BK virus infection and/or a BK virus associated disorder.

9. A nucleic acid encoding the antibody heavy and/or light chain variable region  
25 of the antibody molecule or binding fragment thereof of any one of claims 1-6.

10. An expression vector comprising the nucleic acid of claim 9.

11. A host cell comprising the nucleic acid of claim 9 or the expression vector of  
claim 10.

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12. A method of producing an antibody molecule, the method comprising culturing the host cell of claim 11 under conditions suitable for gene expression.

13. A diagnostic composition comprising the antibody molecule or binding  
35 fragment thereof of any one of claims 1-6.