FIG. 1A: The cDNA (SEQ ID NO:1) and amino acid sequence (SEQ ID NO:2) of 191P4D12. The start methionine is underlined. The open reading frame extends from nucleic acid 264-1796 including the stop codon.

```
   1 ggccgtcgttgttggccacagcgtgggaagcagctctgggggagctcggagctcccgatc
  61 acggcttcttgggggtagctacggctgggtgtgtagaacggggccggggctggggctggg
 121 tcccctagtggagacccaagtgcgagaggcaagaactctgcagcttcctgccttctgggt
 181 cagttccttattcaagtctgcagccggctcccagggagatctcggtggaacttcagaaac
   1                     M  P  L  S  L  G  A  E  M  W  G  P  E
 241 gctgggcagtctgcctttcaaccATGCCCCTGTCCCTGGGAGCCGAGATGTGGGGGCCTG
  14   A  W  L  L  L  L  L  L  A  S  F  T  G  R  C  P  A  G  E
 301 AGGCCTGGCTGCTGCTGCTGCTACTGCTGGCATCATTTACAGGCCGGTGCCCCGCGGGTG
  34   L  E  T  S  D  V  V  T  V  V  L  G  Q  D  A  K  L  P  C  F
 361 AGCTGGAGACCTCAGACGTGGTAACTGTGGTGCTGGGCCAGGACGCAAAACTGCCCTGCT
  54   Y  R  G  D  S  G  E  Q  V  G  Q  V  A  W  A  R  V  D  A  G
 421 TCTACCGAGGGGACTCCGGCGAGCAAGTGGGGCAAGTGGCATGGGCTCGGGTGGACGCGG
  74   E  G  A  Q  E  L  A  L  L  H  S  K  Y  G  L  H  V  S  P  A
 481 GCGAAGGCGCCCAGGAACTAGCGCTACTGCACTCCAAATACGGGCTTCATGTGAGCCCGG
  94   Y  E  G  R  V  E  Q  P  P  P  P  R  N  P  L  D  G  S  V  L
 541 CTTACGAGGGCCGCGTGGAGCAGCCGCCGCCCCCACGCAACCCCCTGGACGGCTCAGTGC
 114   L  R  N  A  V  Q  A  D  E  G  E  Y  E  C  R  V  S  T  F  P
 601 TCCTGCGCAACGCAGTGCAGGCGGATGAGGGCGAGTACGAGTGCCGGGTCAGCACCTTCC
 134   A  G  S  F  Q  A  R  L  R  L  R  V  L  V  P  P  L  P  S  L
 661 CCGCCGGCAGCTTCCAGGCGCGGCTGCGGCTCCGAGTGCTGGTGCCTCCCCTGCCCTCAC
 154   N  P  G  P  A  L  E  E  G  Q  G  L  T  L  A  A  S  C  T  A
 721 TGAATCCTGGTCCAGCACTAGAAGAGGGCCAGGGCCTGACCCTGGCAGCCTCCTGCACAG
 174   E  G  S  P  A  P  S  V  T  W  D  T  E  V  K  G  T  T  S  S
 781 CTGAGGGCAGCCCAGCCCCCAGCGTGACCTGGGACACGGAGGTCAAAGGCACAACGTCCA
 194   R  S  F  K  H  S  R  S  A  A  V  T  S  E  F  H  L  V  P  S
 841 GCCGTTCCTTCAAGCACTCCCGCTCTGCTGCCGTCACCTCAGAGTTCCACTTGGTGCCTA
 214   R  S  M  N  G  Q  P  L  T  C  V  V  S  H  P  G  L  L  Q  D
 901 GCCGCAGCATGAATGGGCAGCCACTGACTTGTGTGGTGTCCCATCCTGGCCTGCTCCAGG
 234   Q  R  I  T  H  I  L  H  V  S  F  L  A  E  A  S  V  R  G  L
 961 ACCAAAGGATCACCCACATCCTCCACGTGTCCTTCCTTGCTGAGGCCTCTGTGAGGGGCC
 254   E  D  Q  N  L  W  H  I  G  R  E  G  A  M  L  K  C  L  S  E
1021 TTGAAGACCAAAATCTGTGGCACATTGGCAGAGAAGGAGCTATGCTCAAGTGCCTGAGTG
 274   G  Q  P  P  P  S  Y  N  W  T  R  L  D  G  P  L  P  S  G  V
1081 AAGGGCAGCCCCCTCCCTCATACAACTGGACACGGCTGGATGGGCCTCTGCCCAGTGGGG
 294   R  V  D  G  D  T  L  G  F  P  P  L  T  T  E  H  S  G  I  Y
1141 TACGAGTGGATGGGGACACTTTGGGCTTTCCCCCACTGACCACTGAGCACAGCGGCATCT
 314   V  C  H  V  S  N  E  F  S  S  R  D  S  Q  V  T  V  D  V  L
1201 ACGTCTGCCATGTCAGCAATGAGTTCTCCTCAAGGGATTCTCAGGTCACTGTGGATGTTC
 334   D  P  Q  E  D  S  G  K  Q  V  D  L  V  S  A  S  V  V  V  V
```

```
1261 TTGACCCCCAGGAAGACTCTGGGAAGCAGGTGGACCTAGTGTCAGCCTCGGTGGTGGTGG
 354   G  V  I  A  A  L  L  F  C  L  L  V  V  V  V  V  L  M  S  R
1321 TGGGTGTGATCGCCGCACTCTTGTTCTGCCTTCTGGTGGTGGTGGTGGTGCTCATGTCCC
 374   Y  H  R  R  K  A  Q  Q  M  T  Q  K  Y  E  E  E  L  T  L  T
1381 GATACCATCGGCGCAAGGCCCAGCAGATGACCCAGAAATATGAGGAGGAGCTGACCCTGA
 394   R  E  N  S  I  R  R  L  H  S  H  H  T  D  P  R  S  Q  P  E
1441 CCAGGGAGAACTCCATCCGGAGGCTGCATTCCCATCACACGGACCCCAGGAGCCAGCCGG
 414   E  S  V  G  L  R  A  E  G  H  P  D  S  L  K  D  N  S  S  C
1501 AGGAGAGTGTAGGGCTGAGAGCCGAGGGCCACCCTGATAGTCTCAAGGACAACAGTAGCT
 434   S  V  M  S  E  E  P  E  G  R  S  Y  S  T  L  T  T  V  R  E
1561 GCTCTGTGATGAGTGAAGAGCCCGAGGGCCGCAGTTACTCCACGCTGACCACGGTGAGGG
 454   I  E  T  Q  T  E  L  L  S  P  G  S  G  R  A  E  E  E  E  D
1621 AGATAGAAACACAGACTGAACTGCTGTCTCCAGGCTCTGGGCGGGCCGAGGAGGAGGAAG
 474   Q  D  E  G  I  K  Q  A  M  N  H  F  V  Q  E  N  G  T  L  R
1681 ATCAGGATGAAGGCATCAAACAGGCCATGAACCATTTTGTTCAGGAGAATGGGACCCTAC
 494   A  K  P  T  G  N  G  I  Y  I  N  G  R  G  H  L  V  *
1741 GGGCCAAGCCCACGGGCAATGGCATCTACATCAATGGGCGGGGACACCTGGTCTGAccca
1801 ggcctgcctcccttccctaggcctggctccttctgttgacatgggagattttagctcatc
1861 ttgggggcctccttaaacacccccatttcttgcggaagatgctccccatcccactgactg
1921 cttgacctttacctccaacccttctgttcatcgggagggctccaccaattgagtctctcc
1981 caccatgcatgcaggtcactgtgtgtgtgcatgtgtgcctgtgtgagtgttgactgactg
2041 tgtgtgtgtggaggggtgactgtccgtggaggggtgactgtgtccgtggtgtgtattatg
2101 ctgtcatatcagagtcaagtgaactgtggtgtatgtgccacgggatttgagtggttgcgt
2161 gggcaacactgtcagggtttggcgtgtgtgtcatgtggctgtgtgtgacctctgcctgaa
2221 aaagcaggtattttctcagaccccagagcagtattaatgatgcagaggttggaggagaga
2281 ggtggagactgtggctcagacccaggtgtgcgggcatagctggagctggaatctgcctcc
2341 ggtgtgagggaacctgtctcctaccacttcggagccatgggggcaagtgtgaagcagcca
2401 gtccctgggtcagccagaggcttgaactgttacagaagccctctgccctctggtggcctc
2461 tgggcctgctgcatgtacatattttctgtaaatatacatgcgccgggagcttcttgcagg
2521 aatactgctccgaatcacttttaatttttttctttttttttttcttgccctttccattagt
2581 tgtatttttttatttatttttatttttatttttttttagagatggagtctcactatgttgc
2641 tcaggctggccttgaactcctgggctcaagcaatcctcctgcctcagcctccctagtagc
2701 tgggactttaagtgtacaccactgtgcctgctttgaatcctttacgaagagaaaaaaaaa
2761 attaaagaaagcctttagatttatccaatgtttactactgggattgcttaaagtgaggcc
2821 cctccaacaccaggggttaattcctgtgattgtgaaaggggctacttccaaggcatctt
2881 catgcaggcagccccttgggagggcacctgagagctggtagagtctgaaattagggatgt
2941 gagcctcgtggttactgagtaaggtaaaattgcatccaccattgtttgtgataccttagg
3001 gaattgcttggacctggtgacaagggctcctgttcaatagtggtgttggggagagagaga
3061 gcagtgattatagaccgagagagtaggagttgaggtgaggtgaaggaggtgctgggggtg
3121 agaatgtcgccttttccccctgggttttggatcactaattcaaggctcttctggatgtttc
3181 tctgggttggggctggagttcaatgaggtttatttttagctggcccacccagatacactc
3241 agccagaatacctagatttagtacccaaactcttcttagtctgaaatctgctggatttct
3301 ggcctaagggagaggctcccatccttcgttccccagccagcctaggacttcgaatgtgga
3361 gcctgaagatctaagatcctaacatgtacattttatgtaaatatgtgcatatttgtacat
3421 aaaatgatattctgtttttaaataaacagacaaaacttgaaaaa
```

FIG. 1A
(Continued)

FIG. 1B: The cDNA (SEQ ID NO:3) and amino acid sequence (SEQ ID NO:4) of Ha22-2(2,4)6.1 heavy chain. Double-underlined is the leader sequence, underlined is the heavy chain variable region, and underlined with a dashed line is the human IgG1 constant region.

```
                                                M  E  L  G  L  C  W  V  F  L  V  A  I  L  E
   1 GGTGATCAGCACTGAACACAGAGGACTCACCATGGAGTTGGGGCTGTGCTGGGTTTTCCTTGTTGCTATTTTAGA
       ·G  V  Q  C  E  V  Q  L  V  E  S  G  G  G  L  V  Q  P  G  G  S  L  R  L  S
  76 AGGTGTCCAGTGTGAGGTGCAGCTGGTGGAGTCTGGGGGAGGCTTGGTACAGCCTGGGGGGTCCCTGAGACTCTC
       ·C  A  A  S  G  F  T  F  S  S  Y  N  M  N  W  V  R  Q  A  P  G  K  G  L  E
 151 CTGTGCAGCCTCTGGATTCACCTTCAGTAGCTATAACATGAACTGGGTCCGCCAGGCTCCAGGGAAGGGGCTGGA
       ·W  V  S  Y  I  S  S  S  S  S  T  I  Y  Y  A  D  S  V  K  G  R  F  T  I  S
 226 GTGGGTTTCATACATTAGTAGTAGTAGTAGTACCATATACTACGCAGACTCTGTGAAGGGCCGATTCACCATCTC
       ·R  D  N  A  K  N  S  L  S  L  Q  M  N  S  L  R  D  E  D  T  A  V  Y  Y  C
 301 CAGAGACAATGCCAAGAACTCACTGTCTCTGCAAATGAACAGCCTGAGAGACGAGGACACGGCTGTGTATTACTG
       ·A  R  A  Y  Y  Y  G  M  D  V  W  G  Q  G  T  T  V  T  V  S  S  A  S  T  K
 376 TGCGAGAGCATACTACTACGGTATGGACGTCTGGGGCCAAGGGACCACGGTCACCGTCTCCTCAGCCTCCACCAA
       ·G  P  S  V  F  P  L  A  P  S  S  K  S  T  S  G  G  T  A  A  L  G  C  L  V
 451 GGGCCCATCGGTCTTCCCCCTGGCACCCTCCTCCAAGAGCACCTCTGGGGGCACAGCGGCCCTGGGCTGCCTGGT
       ·K  D  Y  F  P  E  P  V  T  V  S  W  N  S  G  A  L  T  S  G  V  H  T  F  P
 526 CAAGGACTACTTCCCCGAACCGGTGACGGTGTCGTGGAACTCAGGCGCCCTGACCAGCGGCGTGCACACCTTCCC
       ·A  V  L  Q  S  S  G  L  Y  S  L  S  S  V  V  T  V  P  S  S  S  L  G  T  Q
 601 GGCTGTCCTACAGTCCTCAGGACTCTACTCCCTCAGCAGCGTGGTGACCGTGCCCTCCAGCAGCTTGGGCACCCA
       ·T  Y  I  C  N  V  N  H  K  P  S  N  T  K  V  D  K  R  V  E  P  K  S  C  D
 676 GACCTACATCTGCAACGTGAATCACAAGCCCAGCAACACCAAGGTGGACAAGAGAGTTGAGCCCAAATCTTGTGA
       ·K  T  H  T  C  P  P  C  P  A  P  E  L  L  G  G  P  S  V  F  L  F  P  P  K
 751 CAAAACTCACACATGCCCACCGTGCCCAGCACCTGAACTCCTGGGGGGACCGTCAGTCTTCCTCTTCCCCCCAAA
       ·P  K  D  T  L  M  I  S  R  T  P  E  V  T  C  V  V  V  D  V  S  H  E  D  P
 826 ACCCAAGGACACCCTCATGATCTCCCGGACCCCTGAGGTCACATGCGTGGTGGTGGACGTGAGCCACGAAGACCC
       ·E  V  K  F  N  W  Y  V  D  G  V  E  V  H  N  A  K  T  K  P  R  E  E  Q  Y
 901 TGAGGTCAAGTTCAACTGGTACGTGGACGGCGTGGAGGTGCATAATGCCAAGACAAAGCCGCGGGAGGAGCAGTA
       ·N  S  T  Y  R  V  V  S  V  L  T  V  L  H  Q  D  W  L  N  G  K  E  Y  K  C
 976 CAACAGCACGTACCGTGTGGTCAGCGTCCTCACCGTCCTGCACCAGGACTGGCTGAATGGCAAGGAGTACAAGTG
       ·K  V  S  N  K  A  L  P  A  P  I  E  K  T  I  S  K  A  K  G  Q  P  R  E  P
1051 CAAGGTCTCCAACAAAGCCCTCCCAGCCCCCATCGAGAAAACCATCTCCAAAGCCAAAGGGCAGCCCCGAGAACC
       ·Q  V  Y  T  L  P  P  S  R  E  E  M  T  K  N  Q  V  S  L  T  C  L  V  K  G
1126 ACAGGTGTACACCCTGCCCCCATCCCGGGAGGAGATGACCAAGAACCAGGTCAGCCTGACCTGCCTGGTCAAAGG
       ·F  Y  P  S  D  I  A  V  E  W  E  S  N  G  Q  P  E  N  N  Y  K  T  T  P  P
1201 CTTCTATCCCAGCGACATCGCCGTGGAGTGGGAGAGCAATGGGCAGCCGGAGAACAACTACAAGACCACGCCTCC
       ·V  L  D  S  D  G  S  F  F  L  Y  S  K  L  T  V  D  K  S  R  W  Q  Q  G  N
1276 CGTGCTGGACTCCGACGGCTCCTTCTTCCTCTATAGCAAGCTCACCGTGGACAAGAGCAGGTGGCAGCAGGGGAA
       ·V  F  S  C  S  V  M  H  E  A  L  H  N  H  Y  T  Q  K  S  L  S  L  S  P  G
1351 CGTCTTCTCATGCTCCGTGATGCATGAGGCTCTGCACAACCACTACACGCAGAAGAGCCTCTCCCTGTCCCCGGG
       ·K  *
1426 TAAATGA
```

FIG. 1C: The cDNA (SEQ ID NO:5) and amino acid sequence (SEQ ID NO:6) of Ha22-2(2,4)6.1 light chain. Double-underlined is the leader sequence, underlined is the light chain variable region, and underlined with a dashed line is the human kappa constant region.

```
                                                M  D  M  R  V  P  A  Q  L  L  G  L  L  L  L  W  F
   1 AGTCAGACCCAGTCAGGACACAGCATGGACATGAGGGTCCCCGCTCAGCTCCTGGGGCTCCTGCTGCTCTGGTTC
       P  G  S  R  C  D  I  Q  M  T  Q  S  P  S  S  V  S  A  S  V  G  D  R  V  T
  76 CCAGGTTCCAGATGCGACATCCAGATGACCCAGTCTCCATCTTCCGTGTCTGCATCTGTTGGAGACAGAGTCACC
       I  T  C  R  A  S  Q  G  I  S  G  W  L  A  W  Y  Q  Q  K  P  G  K  A  P  K
 151 ATCACTTGTCGGGCGAGTCAGGGTATTAGCGGCTGGTTAGCCTGGTATCAGCAGAAACCAGGGAAAGCCCCTAAG
       F  L  I  Y  A  A  S  T  L  Q  S  G  V  P  S  R  F  S  G  S  G  S  G  T  D
 226 TTCCTGATCTATGCTGCATCCACTTTGCAAAGTGGGGTCCCATCAAGGTTCAGCGGCAGTGGATCTGGGACAGAT
       F  T  L  T  I  S  S  L  Q  P  E  D  F  A  T  Y  Y  C  Q  Q  A  N  S  F  P
 301 TTCACTCTCACCATCAGCAGCCTGCAGCCTGAAGATTTTGCAACTTACTATTGTCAACAGGCTAACAGTTTCCCT
       P  T  F  G  G  G  T  K  V  E  I  K  R  T  V  A  A  P  S  V  F  I  F  P  P
 376 CCCACTTTCGGCGGAGGGACCAAGGTGGAGATCAAACGAACTGTGGCTGCACCATCTGTCTTCATCTTCCCGCCA
       S  D  E  Q  L  K  S  G  T  A  S  V  V  C  L  L  N  N  F  Y  P  R  E  A  K
 451 TCTGATGAGCAGTTGAAATCTGGAACTGCCTCTGTTGTGTGCCTGCTGAATAACTTCTATCCCAGAGAGGCCAAA
       V  Q  W  K  V  D  N  A  L  Q  S  G  N  S  Q  E  S  V  T  E  Q  D  S  K  D
 526 GTACAGTGGAAGGTGGATAACGCCCTCCAATCGGGTAACTCCCAGGAGAGTGTCACAGAGCAGGACAGCAAGGAC
       S  T  Y  S  L  S  S  T  L  T  L  S  K  A  D  Y  E  K  H  K  V  Y  A  C  E
 601 AGCACCTACAGCCTCAGCAGCACCCTGACGCTGAGCAAAGCAGACTACGAGAAACACAAAGTCTACGCCTGCGAA
       V  T  H  Q  G  L  S  S  P  V  T  K  S  F  N  R  G  E  C  *
 676 GTCACCCATCAGGGCCTGAGCTCGCCCGTCACAAAGAGCTTCAACAGGGGAGAGTGTTAG
```

FIG. 1D: The amino acid sequence (SEQ ID NO:7) of Ha22-2(2,4)6.1 heavy chain. Double-underlined is the leader sequence, underlined is the heavy chain variable region, (SEQ ID NO:22, which is the sequence ranging from the 20th to the 136th amino acid of SEQ ID NO:7) and underlined with a dashed line is the human IgG1 constant region.

```
  1 MELGLCWVFLVAILEGVQCEVQLVESGGGLVQPGGSLRLSCAASGFTFSS
 51 YNMNWVRQAPGKGLEWVSYISSSSSTIYYADSVKGRFTISRDNAKNSLSL
101 QMNSLRDEDTAVYYCARAYYYGMDVWGQGTTVTVSSASTKGPSVFPLAPS
151 SKSTSGGTAALGCLVKDYFPEPVTVSWNSGALTSGVHTFPAVLQSSGLYS
201 LSSVVTVPSSSLGTQTYICNVNHKPSNTKVDKRVEPKSCDKTHTCPPCPA
251 PELLGGPSVFLFPPKPKDTLMISRTPEVTCVVVDVSHEDPEVKFNWYVDG
301 VEVHNAKTKPREEQYNSTYRVVSVLTVLHQDWLNGKEYKCKVSNKALPAP
351 IEKTISKAKGQPREPQVYTLPPSREEMTKNQVSLTCLVKGFYPSDIAVEW
401 ESNGQPENNYKTTPPVLDSDGSFFLYSKLTVDKSRWQQGNVFSCSVMHEA
451 LHNHYTQKSLSLSPGK
```

FIG. 1E: The amino acid sequence (SEQ ID NO:8) of Ha22-2(2,4)6.1 light chain. Double-underlined is the leader sequence, underlined is the light chain variable region (SEQ ID NO:23, which is the sequence ranging from the 23rd to the 130th amino acid of SEQ ID NO:8), and underlined with a dashed line is the human kappa constant region.

```
  1 MDMRVPAQLLGLLLLWFPGSRCDIQMTQSPSSVSASVGDRVTITCRASQG
 51 ISGWLAWYQQKPGKAPKFLIYAASTLQSGVPSRFSGSGSGTDFTLTISSL
101 QPEDFATYYCQQANSFPPTFGGGTKVEIKRTVAAPSVFIFPPSDEQLKSG
151 TASVVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDSKDSTYSLSST
201 LTLSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC
```

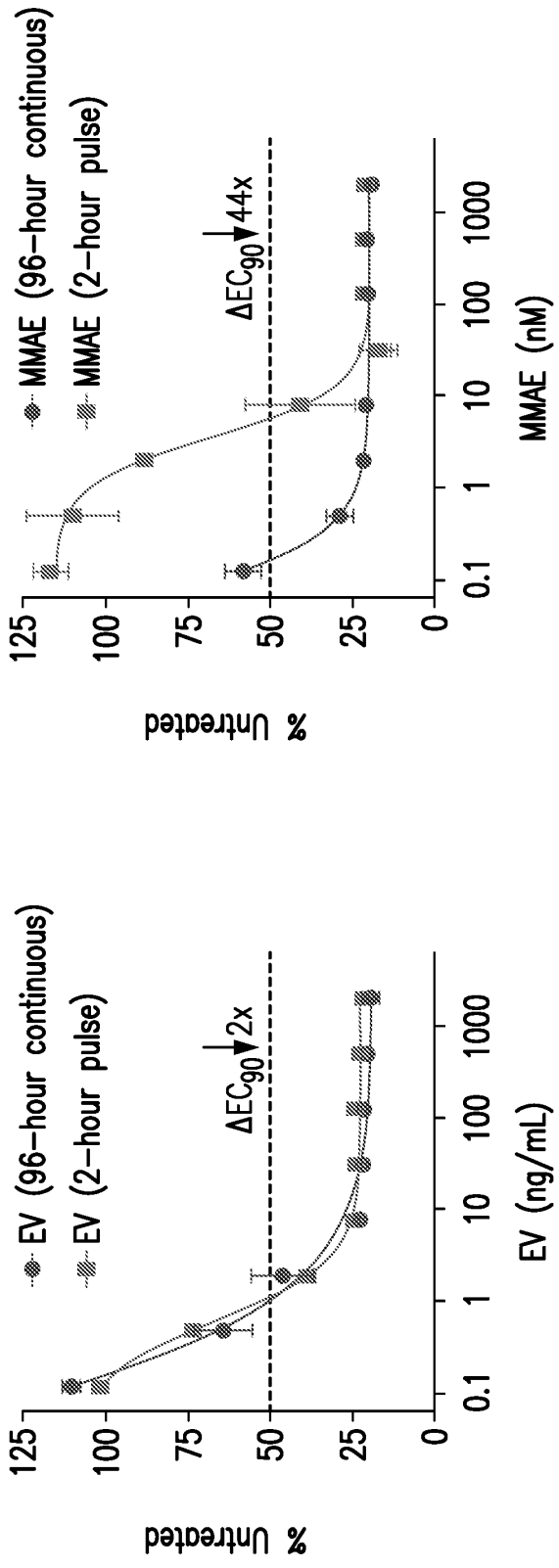

MMAE (96−hour continuous)
MMAE (2−hour pulse)
ΔEC90 44x
% Untreated
MMAE (nM)
EV (96−hour continuous)
EV (2−hour pulse)
ΔEC90 2x
% Untreated
EV (ng/mL)

FIG. 2

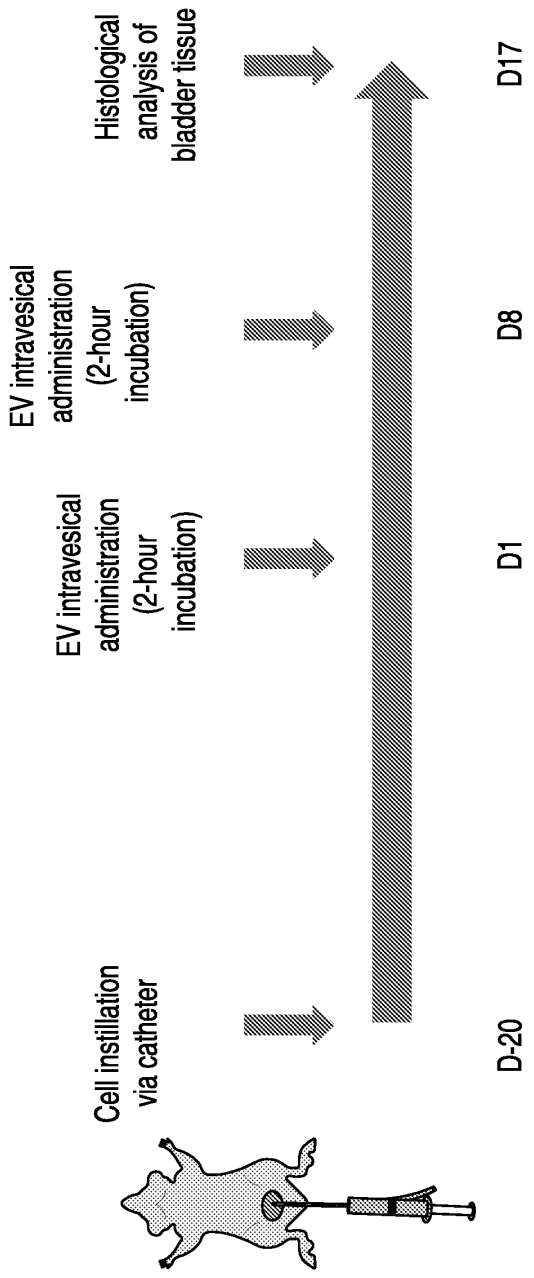

Cell instillation via catheter
EV intravesical administration (2-hour incubation)
EV intravesical administration (2-hour incubation)
Histological analysis of bladder tissue
D-20
D1
D8
D17

FIG. 3A

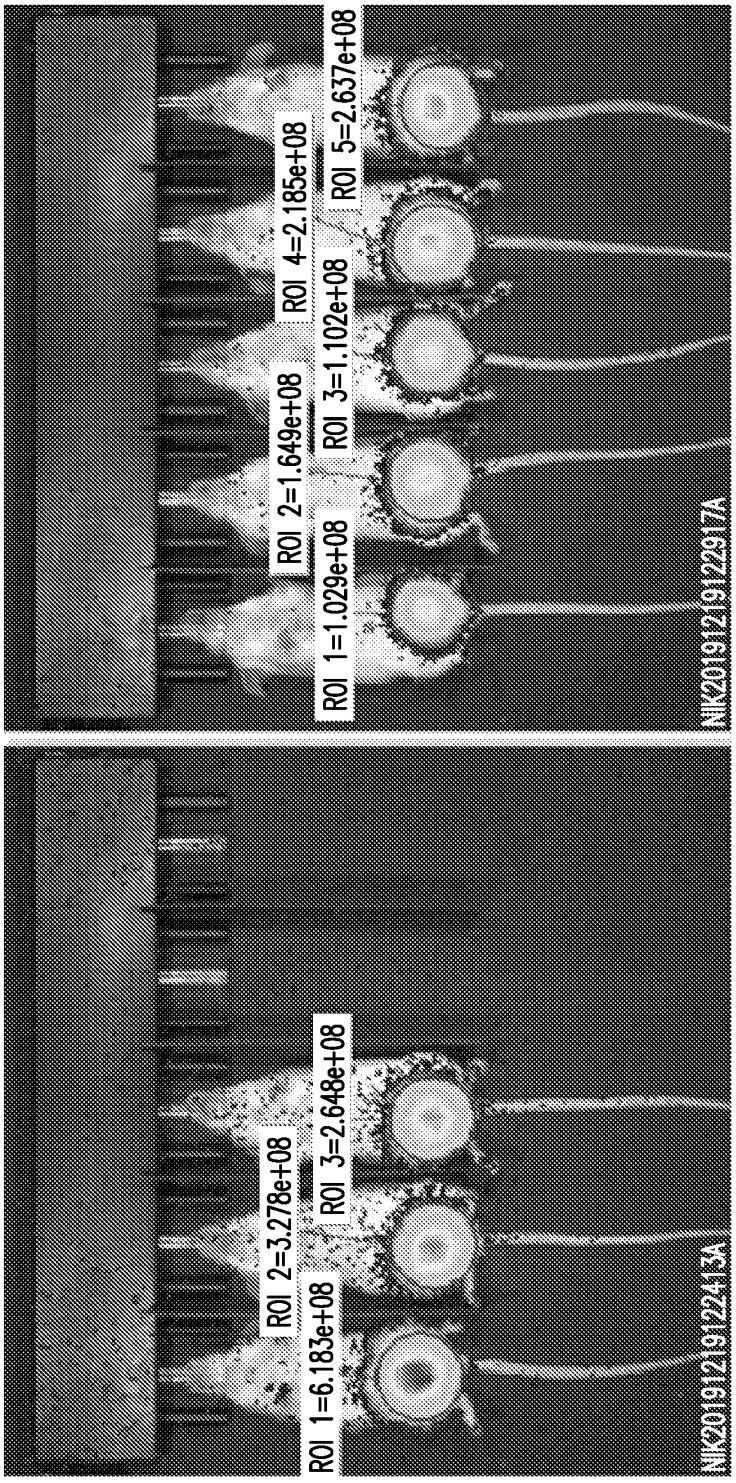

ROI 1=6.183e+08
ROI 2=3.278e+08
ROI 3=2.648e+08
NIK20191219122413A
Untreated
ROI 1=1.029e+08
ROI 2=1.649e+08
ROI 3=1.102e+08
ROI 4=2.185e+08
ROI 5=2.637e+08
NIK20191219122917A
Vehicle (SWFI)
2-hour
Intravesical

FIG. 3B

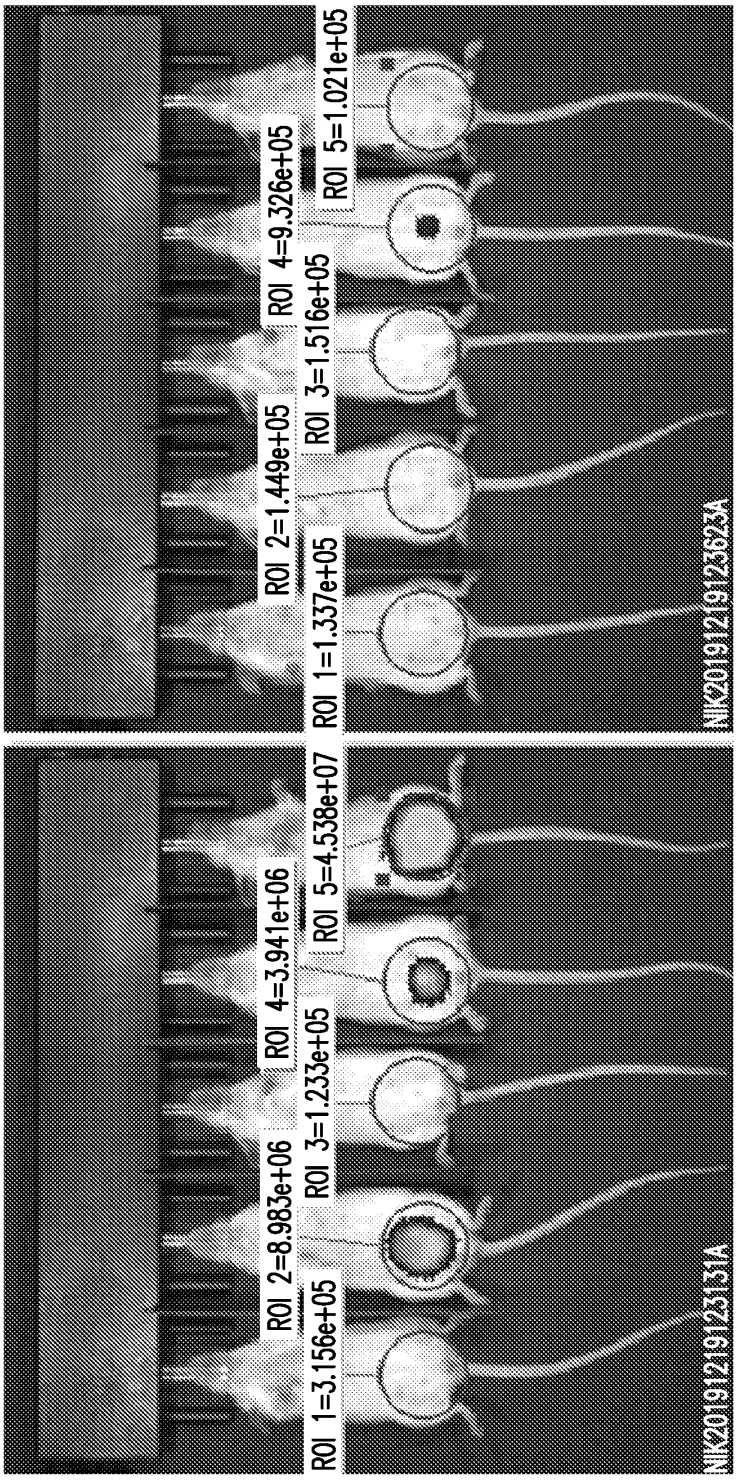


FIG. 3B Continued

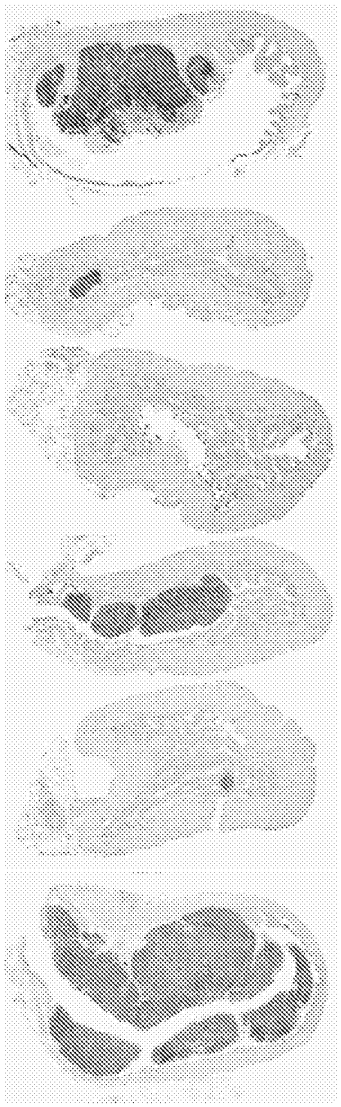


FIG. 3C

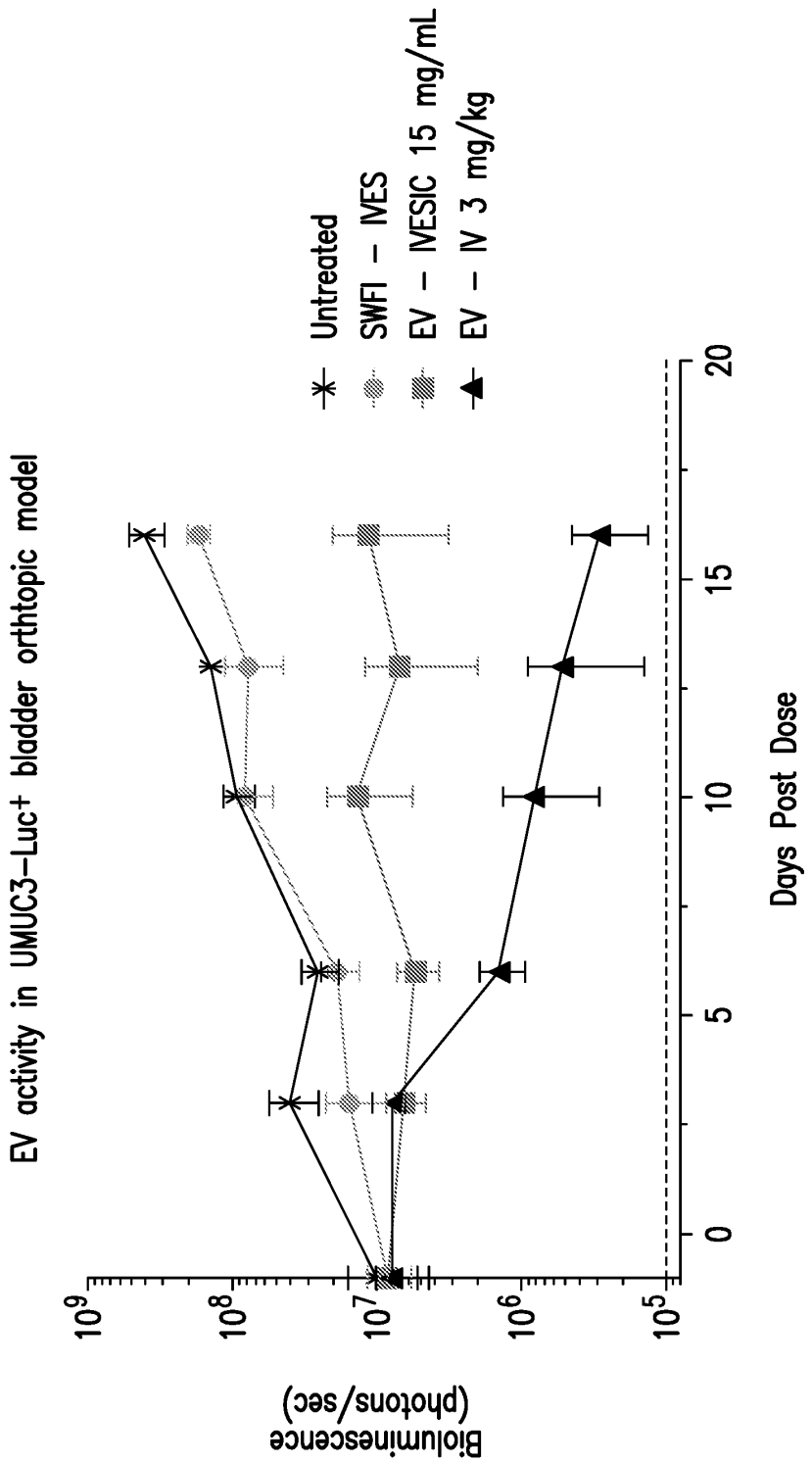

EV activity in UMUC3–Luc+ bladder orthtopic model
Untreated
SWFI – IVES
EV – IVESIC 15 mg/mL
EV – IV 3 mg/kg
Bioluminescence (photons/sec)
10^9
10^8
10^7
10^6
10^5
0
5
10
15
20
Days Post Dose

FIG. 3D

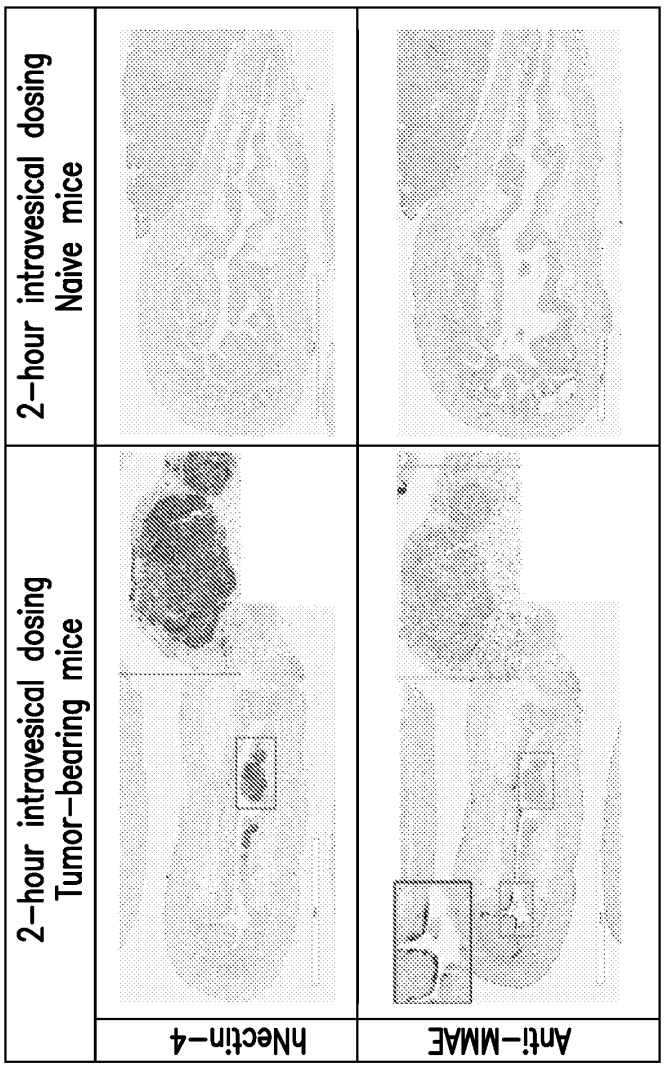

2-hour intravesical dosing
Tumor-bearing mice
2-hour intravesical dosing
Naive mice
hNectin-4
Anti-MMAE

FIG. 3E

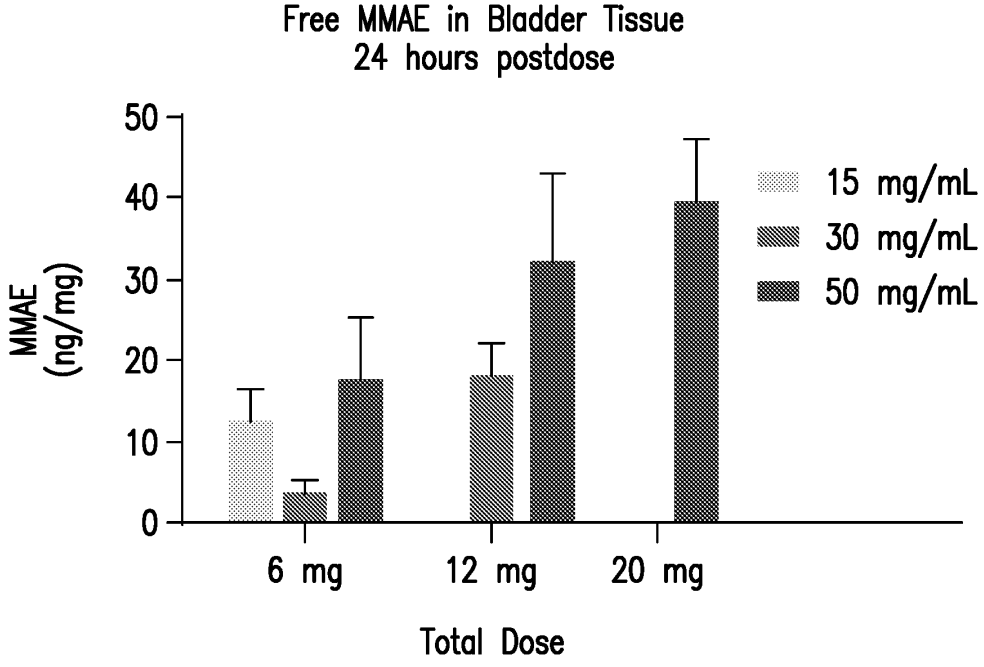

Free MMAE in Bladder Tissue
24 hours postdose
MMAE (ng/mg)
50
40
30
20
10
0
15 mg/mL
30 mg/mL
50 mg/mL
6 mg
12 mg
20 mg
Total Dose

FIG. 4A

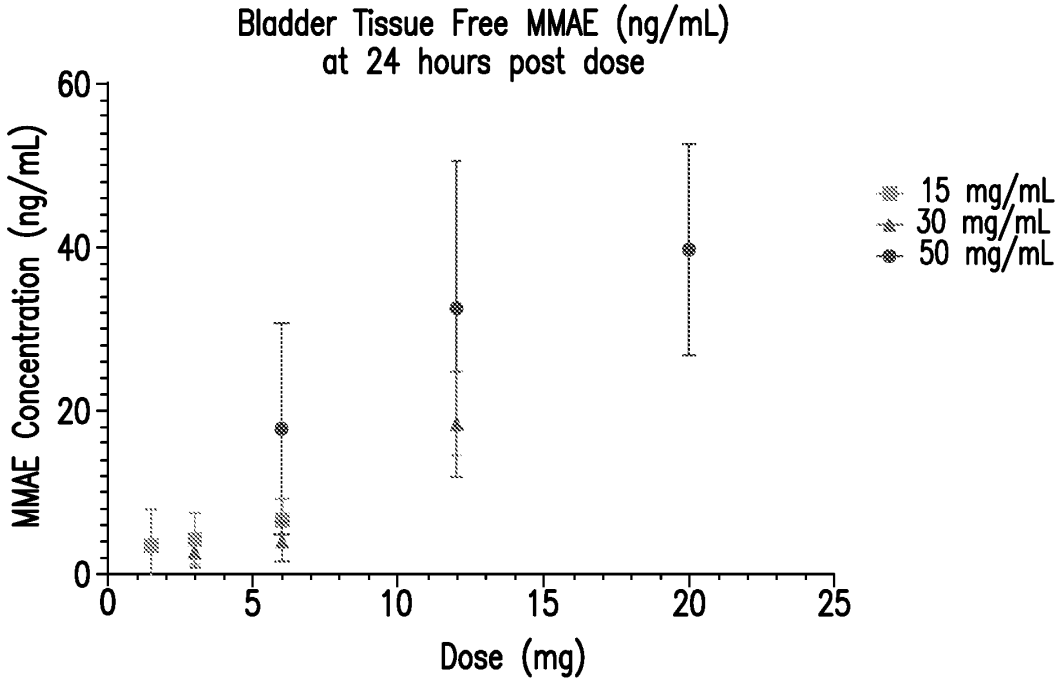

Bladder Tissue Free MMAE (ng/mL)
at 24 hours post dose
MMAE Concentration (ng/mL)
60
40
20
0
0
5
10
15
20
25
Dose (mg)
15 mg/mL
30 mg/mL
50 mg/mL

FIG. 4B

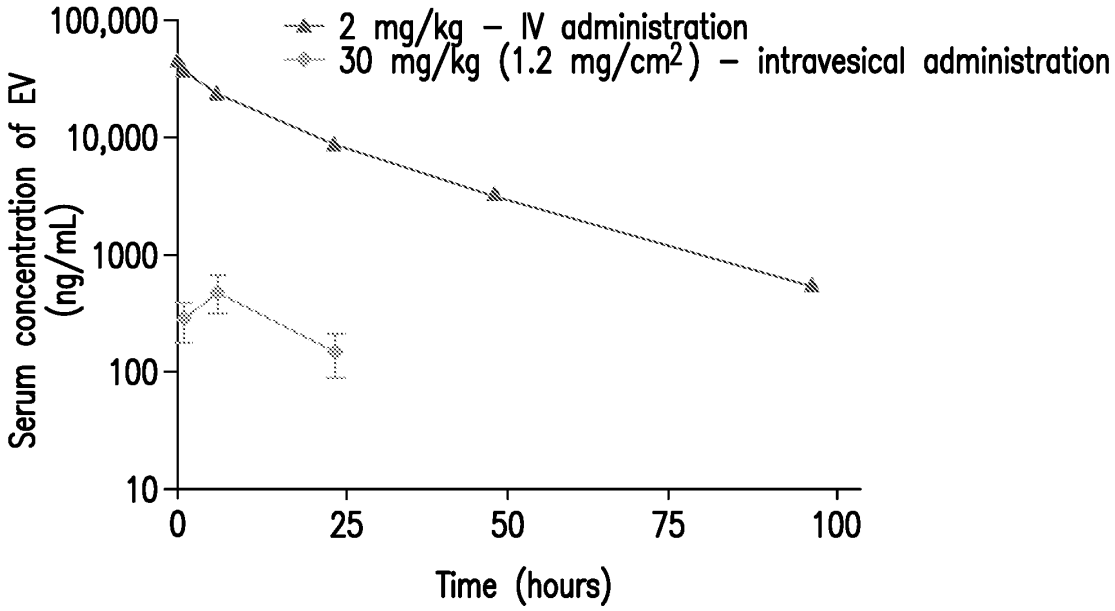

2 mg/kg – IV administration
30 mg/kg (1.2 mg/cm2) – intravesical administration
Serum concentration of EV (ng/mL)
100,000
10,000
1000
100
10
0
25
50
75
100
Time (hours)

FIG. 5

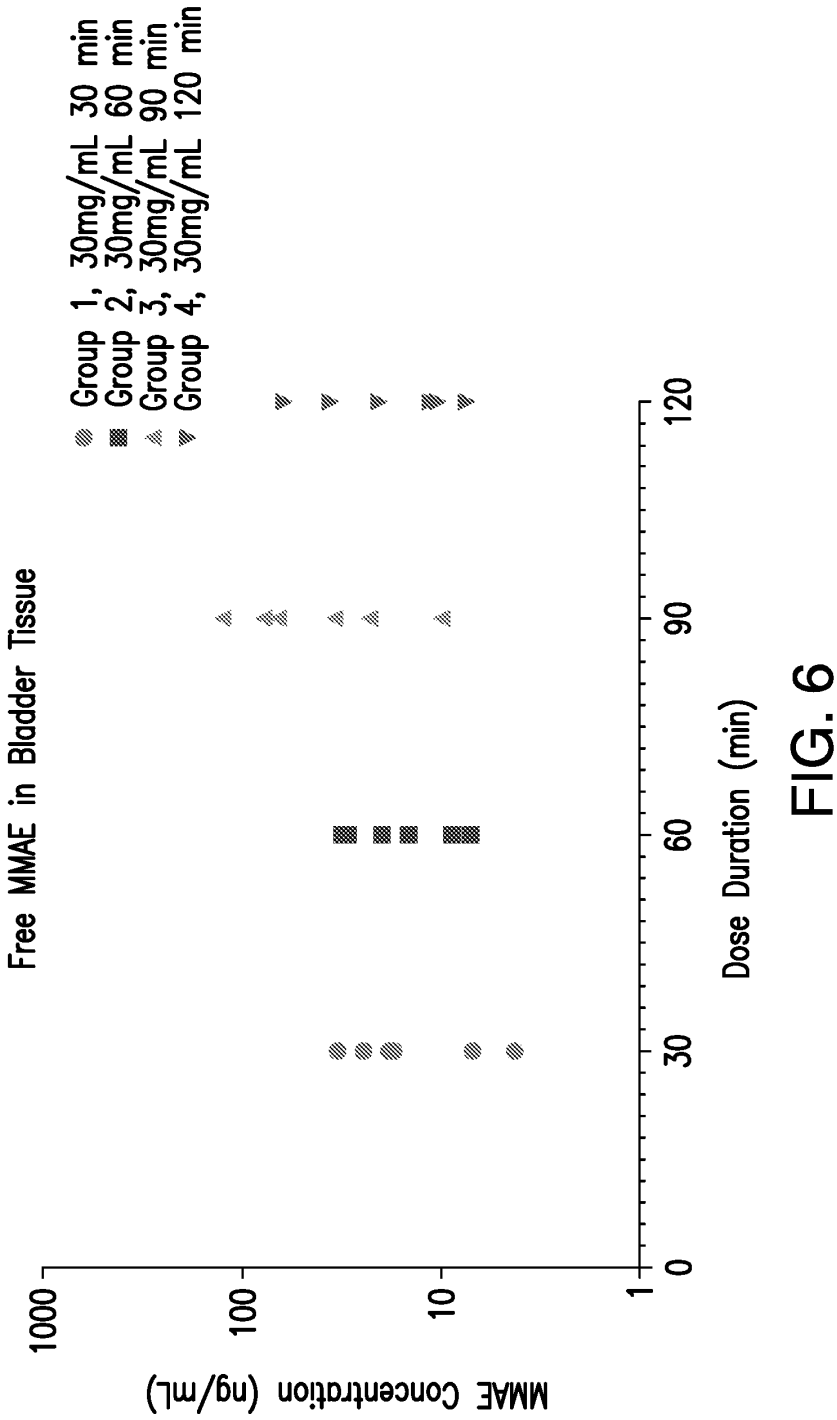

Free MMAE in Bladder Tissue
Group 1, 30mg/mL 30 min
Group 2, 30mg/mL 60 min
Group 3, 30mg/mL 90 min
Group 4, 30mg/mL 120 min
MMAE Concentration (ng/mL)
1000
100
10
1
0
30
60
90
120
Dose Duration (min)

FIG. 6

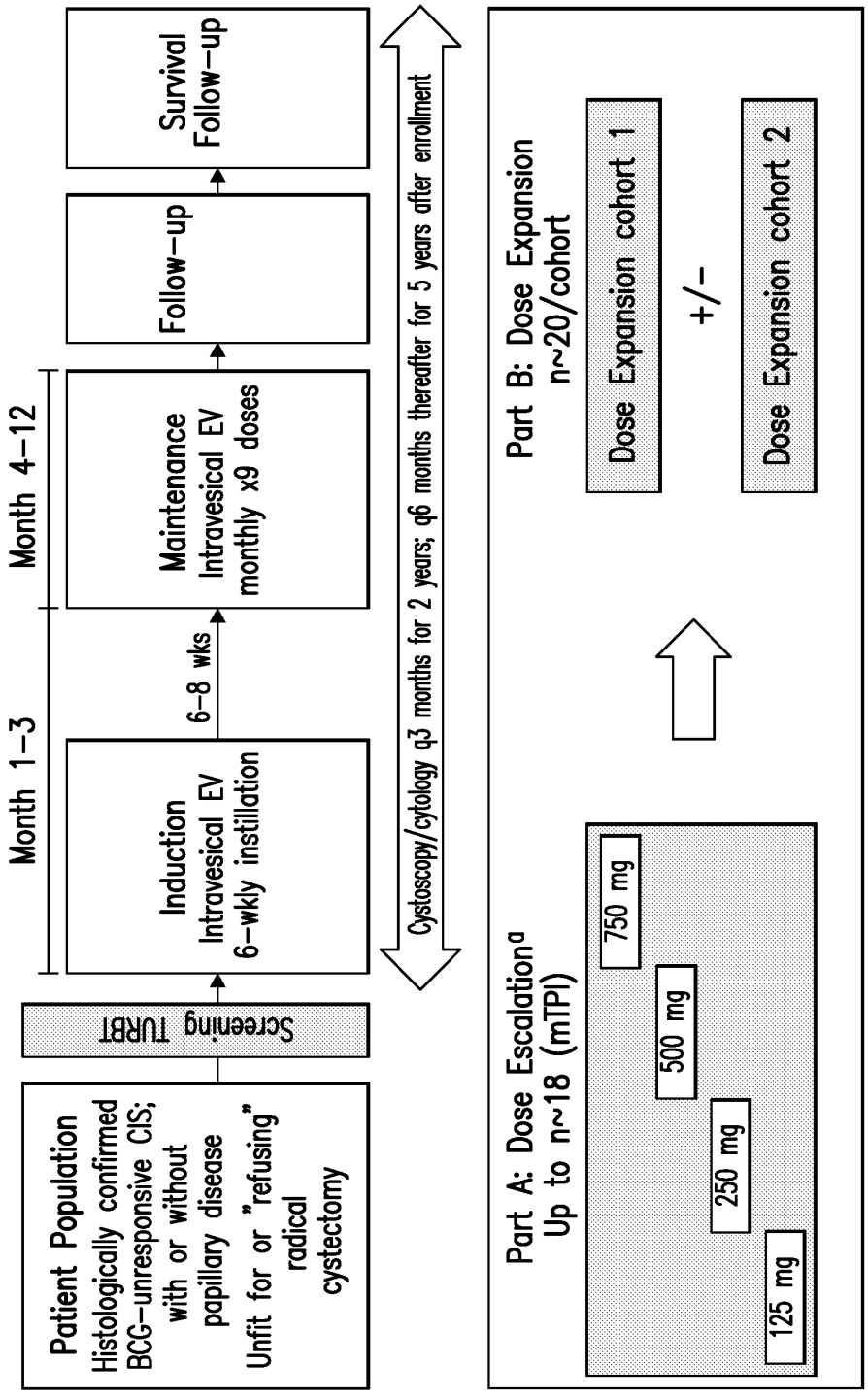

Patient Population
Histologically confirmed BCG-unresponsive CIS; with or without papillary disease
Unfit for or "refusing" radical cystectomy
Screening TURBT
Induction
Intravesical EV
6-wkly instillation
6-8 wks
Maintenance
Intravesical EV
monthly x9 doses
Follow-up
Survival
Follow-up
Month 1-3
Month 4-12
Cystoscopy/cytology q3 months for 2 years; q6 months thereafter for 5 years after enrollment
Part A: Dose Escalation[a]
Up to n~18 (mTPI)
125 mg
250 mg
500 mg
750 mg
Part B: Dose Expansion
n~20/cohort
Dose Expansion cohort 1
+/-
Dose Expansion cohort 2

FIG. 7