CLAIMS

What is claimed is:

1. Use of an agent in the manufacture of a medicament for stimulating the host immune defence mechanism in a subject to attack neoplastic cells to treat, alleviate, ameliorate, relieve, delay onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in the subject; wherein said medicament is to be administered to said subject; and wherein said agent comprises:
    a. a p62/SQSTM1 polypeptide; or,
    b. a p62/SQSTM1 encoding nucleic acid.

2. The use of claim 1 wherein said agent comprises
    a. one or more domain deletions;
    b. wherein said p62/SQSTM1 encoding nucleic acid is at least 95% identical to SEQ ID NO. 1; or
    c. wherein said p62/SQSTM1 polypeptide is at least 98% identical to SEQ ID NO: 2.

3. The use of claim 2 wherein said one or more domain deletions is selected from the group consisting of PB1, ZZ, NLS2, TB, NLS1, NES, LIR, KIR, and UBA.

4. Use of an agent in the manufacture of a medicament for stimulating the host immune defence mechanism in a subject to attack neoplastic cells to treat, alleviate, ameliorate, relieve, delay onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in the subject; wherein said medicament is to be administered to said subject; and wherein said agent comprises:
    a. a p62/SQSTM1 polypeptide at least 90% identical to SEQ ID NO. 2; or,
    b. a p62/SQSTM1 nucleic acid that encodes a polypeptide at least 90% identical to SEQ ID NO: 2.

5. The use of claim 4 where said agent comprises one or more domain deletions.

6. The use of claim 5 wherein said one or more domain deletions is selected from the group consisting of PB1, ZZ, NLS2, TB, NLS1, NES, LIR, KIR, and UBA.

7. Use of an agent in the manufacture of a medicament for stimulating the host immune defence mechanism in a subject to attack neoplastic cells to treat, alleviate, ameliorate, relieve, delay

onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in the subject; wherein said medicament is to be administered to said subject; and wherein said agent comprises:

a. at least 30 consecutive amino acids of a p62/SQSTM1 polypeptide; or,

b. a p62/SQSTM1 encoding nucleic acid, wherein said p62/SQSTM1 encoding nucleic acid encodes at least 30 consecutive amino acids of a p62/SQSTM1 polypeptide.

8. The use of any of claims 1-7 wherein said p62/SQSTM1 polypeptide or p62/SQSTM1 encoding nucleic acid further comprises a fusion polypeptide or nucleic acid encoding for a fusion polypeptide, respectively.

9. The use of any of claims 1-8, further comprising an to be administered adjuvant to said subject.

10. The use of claim 9 wherein said adjuvant is selected from the group consisting of: gel-type, microbial, particulate, oil-emulsion, surfactant-based, and synthetic adjuvants.

11. The use of any of claims 1-10, further comprising one or more co-stimulatory components to be administered to said subject.

12. The use of claim 11, wherein said one or more co-stimulatory components is selected from the group consisting of: a cell surface protein, a cytokine, a chemokine, and a signaling molecule.

13. The use of any of claims 1-12, further comprising one or more molecules that block suppressive or negative regulatory immune mechanisms to be administered to said subject.

14. The use of claim 13 wherein said one or more molecules that block suppressive or negative regulatory immune mechanisms is selected from the group consisting of: anti-CTLA-4 antibody, anti-CD25 antibody, anti-CD4 antibody, and IL13Ra2-Fc.

15. The use of any of claims 1-14, further comprising one or more anticancer therapies to be administered to said subject.

16. The use of claim 15 wherein said one or more anticancer therapies is selected from the group consisting of: a chemotherapeutic molecule, radiation, an anti-angiogenic molecule, an antibody, and a biological agent.

17. The use of claim 16 wherein said chemotherapeutic molecule is selected from the group consisting of: cyclophosphamide, doxorubicin, paclitaxel, docetaxel, vinblastine, methotrexate, navelbine, capecitabine, mitomycin C and 5-fluorouracil.

18. The use according of any claims 1-17, wherein said cancer is a solid tumor cancer.

19. The use of claims 1-18, wherein said solid tumor cancer is selected from the group consisting of: breast cancer, lung cancer, prostate cancer, gastric cancer, colorectal cancer, skin cancer, a cancer of the head and neck, bronchus cancer, pancreatic cancer, urinary bladder cancer, brain cancer, central nervous system cancer, peripheral nervous system cancer, esophageal cancer, cancer of the oral cavity or pharynx, liver cancer, kidney cancer, testicular cancer, biliary tract cancer, small bowel or appendix cancer, ovarian cancer, uterine cancer, salivary gland cancer, thyroid gland cancer, adrenal gland cancer, osteosarcoma, chondrosarcoma, and sarcoma.

20. The use of any claims 1-17, wherein said cancer is cancer of the hematologic tissues.

21. The use of claims 1-20 wherein said subject is selected from the group consisting of: a subject diagnosed with a cancer, a subject previously treated for cancer, a subject with a family history of cancer, and a subject predisposed to cancer.

22. The method of any of claims 1-21, wherein said agent comprises a p62 encoding nucleic acid, wherein said p62 encoded polypeptide is at least 90% identical to SEQ ID NO. 2, and wherein said p62 encoding nucleic acid further comprises a plasmid or a viral vector.

23. The use of any of claims 1-21, wherein said agent comprises a p62/SQSTM1 encoding nucleic acid, and further comprising a strategy for improving the efficiency of nucleic acid-based immunization.

24. The use of claim 23 wherein said strategy is selected from the group consisting of: self-replicating viral replicons, optimizing at least one codon optimization, in vivo electroporation, incorporation of a CpG stimulatory motif, including a sequence for targeting of the endocytic or ubiquitin-processing pathways, including a Marek's disease virus type 1 VP22 sequences, including a prime-boost regimen, and the use of a mucosal delivery vector.

CLAIMS

What is claimed is:

1. Use of an agent for the manufacture of a medicament to treat, alleviate, ameliorate, relieve, delay onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in a subject; wherein said medicament is to be administered to said subject; and wherein said agentcomprises:
    a. a p62 polypeptide; or,
    b. a p62 encoding nucleic acid.
2. The useof claim 1 wherein said agent comprises
    a. one or more domain deletions;
    b. wherein said p62 encoding nucleic acid is at least 95% identical to SEQ ID NO. 1; or
    c. wherein said p62 polypeptide is at least 98% identical to SEQ ID NO: 2
3. The use of claim 2 wherein said one or more domain deletions is selected from the group consisting of PB1, ZZ, NLS2, TB, NLS1, NES, LIR, KIR, and UBA.
4. Use of an agent for the manufacture of a medicament to treat, alleviate, ameliorate, relieve, delay onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in a subject; wherein said medicament is to be administered to said subject; and wherein said agent comprises:
    a. a p62/SQSTM1 polypeptide at least 90% identical to SEQ ID NO. 2; or,
    b. a p62/SQSTM1 nucleic acid that encodes a polypeptide at least 90% identical to SEQ ID NO: 2.
5. The use of claim 4 where said agent comprises one or more domain deletions.
6. The use of claim 5 wherein said one or more domain deletions is selected from the group consisting of PB1, ZZ, NLS2, TB, NLS1, NES, LIR, KIR, and UBA.
7. Use of an agent for the manufacture of a medicament to treat, alleviate, ameliorate, relieve, delay onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in a subject; wherein said medicament is to be administered to said subject; and wherein said agent comprises:
    a. at least 30 amino acids of a p62/SQSTM1 polypeptide; or,
    b. a p62/SQSTM1 encoding nucleic acid, wherein said p62/SQSTM1 encoding nucleic acid encodes at least 30 amino acids of a p62/SQSTM1 polypeptide.
8. The use of any of claims 1-7 wherein said p62 polypeptide or p62 encoding nucleic acid further comprises a fusion polypeptide or nucleic acid encoding for a fusion polypeptide, respectively.

9. The use of any of claims 1-8, further comprising an to be administered adjuvant to said subject.
10. The use of claim 9 wherein said adjuvant is selected from the group consisting of: gel-type, microbial, particulate, oil-emulsion, surfactant-based, and synthetic adjuvants.
11. The use of any of claims 1-10, further comprising one or more co-stimulatory components to be administered to said subject.
12. The use of claim 11, wherein said one or more co-stimulatory components is selected from the group consisting of: a cell surface protein, a cytokine, a chemokine, and a signaling molecule.
13. The use of any of claims 1-12, further comprising one or more molecules that block suppressive or negative regulatory immune mechanisms to be administered to said subject.
14. The use of claim 13 wherein said one or more molecules that block suppressive or negative regulatory immune mechanisms is selected from the group consisting of: anti-CTLA-4 antibody, anti-CD25 antibody, anti-CD4 antibody, and IL13Ra2-Fc.

15. The use of any of claims 1-14, further comprising one or more anticancer therapies to be administered to said subject.
16. The use of claim 15 wherein said one or more anticancer therapies is selected from the group consisting of: a chemotherapeutic molecule, radiation, an anti-angiogenic molecule, an antibody, and a biological agent.
17. The use of claim 16 wherein said chemotherapeutic molecule is selected from the group consisting of: cyclophosphamide, doxorubicin, paclitaxel, docetaxel, vinblastine, methotrexate, navelbine, capecitabine, mitomycin C and 5-fluorouracil.
18. The use according of any claims 1-17, wherein said cancer is a solid tumor cancer.
19. The use of claims 1-18, wherein said solid tumor cancer is selected from the group consisting of: breast cancer, lung cancer, prostate cancer, gastric cancer, colorectal cancer, skin cancer, a cancer of the head and neck, bronchus cancer, pancreatic cancer, urinary bladder cancer, brain cancer, central nervous system cancer, peripheral nervous system cancer, esophageal cancer, cancer of the oral cavity or pharynx, liver cancer, kidney cancer, testicular cancer, biliary tract cancer, small bowel or appendix cancer, ovarian cancer, uterine cancer, salivary gland cancer, thyroid gland cancer, adrenal gland cancer, osteosarcoma, chondrosarcoma, and sarcoma.
20. The use of any claims 1-17, wherein said cancer is cancer of the hematologic tissues.
21. The use of claims 1-20 wherein said subject is selected from the group consisting of: a subject diagnosed with a cancer, a subject previously treated for cancer, a subject with a family history of cancer, and a subject predisposed to cancer.
22. The method of any of claims 1-21, wherein said agent comprises a p62 encoding nucleic acid, wherein said p62 encoded polypeptide is at least 90% identical to SEQ ID NO. 2, and wherein said p62 encoding nucleic acid further comprises a plasmid or a viral vector.
23. The use of any of claims 1-21, wherein said agent comprises a p62 encoding nucleic acid, and further comprising a strategy for improving the efficiency of nucleic acid-based immunization.
24. The use of claim 23 wherein said strategy is selected from the group consisting of: self-replicating viral replicons, optimizing at least one codon optimization, in vivo electroporation, incorporation of a CpG stimulatory motif, including a sequencefor targeting of the endocytic or ubiquitin-processing pathways, including a Marek's disease virus type 1 VP22 sequences, including a prime-boost regimen, and the use of a mucosal delivery vector.

25. An agent to treat, alleviate, ameliorate, relieve, delay onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in a subject comprising:
    a. a p62 polypeptide, or
    b. a p62 encoding nucleic acid.
26. An agent of claim 25 wherein said agent comprises:
    a. one or more domain deletions;
    b. wherein said p62 encoding nucleic acid is at least 95% identical to SEQ ID NO. 1; or
    c. wherein said p62 polypeptide is at least 98% identical to SEQ ID NO: 2.

27. An agent to treat, alleviate, ameliorate, relieve, delay onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in a subject comprising:
    a. a p62/SQSTM1 polypeptide at least 90% identical to SEQ ID NO. 2; or,
        b. a p62/SQSTM1 nucleic acid that encodes a polypeptide at least 90% identical to SEQ ID NO: 2.
28. The agent of claim 27 wherein said agent comprises one or more domain deletions.
29. The agent of claim 28 wherein said one or more domain deletions or domains, respectively, is selected from the group consisting of PB1, ZZ, NLS2, TB, NLS1, NES, LIR, KIR, and UBA.
30. An agent to treat, alleviate, ameliorate, relieve, delay onset of, inhibit progression of, reduce severity of, and/or reduce incidence of one or more symptoms of a cancer in a subject comprising:
    a. at least 30 amino acids of a p62/SQSTM1 polypeptide; or,
        b. a p62/SQSTM1 encoding nucleic acid, wherein said p62/SQSTM1 encoding nucleic acid encodes at least 30 amino acids of a p62/SQSTM1 polypeptide.

31. The agent of any of claims 25-30 wherein said p62 polypeptide or p 62 encoding nucleic acid further comprises a fusion polypeptide or encoding nucleic acid, respectively.

32. The agent of any of claims 25-31, further comprising an adjuvant.
33. The agent of claim 32wherein said adjuvant is selected from the group consisting of: gel-type, microbial, particulate, oil-emulsion, surfactant-based, and synthetic adjuvants.
34. The agent of any of claims 25-33, further comprising administering one or more co-stimulatory components.
35. The agent of claim 34, wherein said one or more co-stimulatory components is selected from the group consisting of: a cell surface protein, cytokine, a chemokineand a signaling molecule.
36. The agent of any of claims 25-35, further comprising administering one or more molecules that block suppressive or negative regulatory immune mechanisms.
37. The agent of claim 36wherein said one or more molecules that block suppressive or negative regulatory immune mechanisms is selected from the group consisting of: anti-CTLA-4 antibody, anti-CD25 antibody, anti-CD4 antibody, and IL13Ra2-Fc.
38. The agent of any of claims 25-37 further comprising a chemotherapeutic molecule or an anti-angiogenic molecule, an antibody, or a biological agent.
39. The agent of claim 38wherein said chemotherapeutic molecule is selected from the group consisting of: cyclophosphamide, doxorubicin, paclitaxel, docetaxel, vinblastine, methotrexate, navelbine, capecitabine, mitomycin C, and 5-fluorouracil.
40. The agent of any of claims 25-39, wherein said agent comprises a p62/SQSTM1 encoding nucleic acid wherein said p62/SQSTM1 encoding nucleic acid further comprises a plasmid or a viral vector.
41. The agent of any of claims 25-40, wherein said agent is a nucleic acid and further includes a nucleic acid selected from the group consisting of: a self-replicating viral replicon, a codon-optimized sequence, a CpG stimulatory motif, a nucleic acid sequence for targeting of the endocytic or ubiquitin-processing pathways, a Marek's disease virus type 1 VP22 sequence, or a mucosal delivery vector.
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