

fluorescent protein (GFP) and luciferase reporter genes. The observed EC_{50} of such redirected killing is about 1.5 $\mu\text{g/mL}$ or less, about 1.0 $\mu\text{g/mL}$ or less, about 500 ng/mL or less, about 300 ng/mL or less, about 200 ng/mL or less, about 100 ng/mL or less, about 50 ng/mL or less.

[0028] The B7-H3 x CD3 bi-specific monovalent Fc diabodies of the present disclosure are preferably capable of mediating the inhibition of human tumor growth in a co-mix xenograft in which such molecules are introduced into NOD/SCID mice along with 22Rv1 (human prostate cancer) or A498 (human kidney cancer) tumor cells and activated human T cells at a ratio of 5:1. Additionally, or alternatively the B7-H3 x CD3 bi-specific monovalent Fc diabodies of the present disclosure are capable of mediating the inhibition of human tumor growth and/or exhibiting anti-tumor activity in a in an xenograft model in female NSG B2m - / - mice:

- (A) implanted with human PBMCs (1×10^7) by intraperitoneal (IP) injection on Day -1 and Detroit (human pharyngeal cancer tumor cells (5×10^6)) intradermally (ID) on Day 0, and administration of diabody on or Days 20, 22, 23, 26, 28, 30, 33, 35, and 37; or
- (B) implanted with A498 (human kidney cancer tumor cells (5×10^6)) intradermally (ID) on Day 0, and human PBMCs (1×10^7) by intraperitoneal (IP) injection on Day 13 and administration of diabody on Days 33, 35, 36, 39, 41, 43, 46, 48, and 50.

[0029] Preferably, the B7-H3 x CD3 bi-specific monovalent Fc diabodies of the present disclosure are capable of inhibiting tumor growth in such xenograft models when provided at a concentration of greater than about 1.0 mg/kg , at a concentration of about 1 mg/kg , at a concentration of about 0.5 mg/kg , at a concentration of about 0.25 mg/kg , at a concentration of about 0.1 mg/kg , at a concentration of about 0.05 mg/kg , at a concentration of about 0.02 mg/kg , at a concentration of about 0.01 mg/kg , or at a concentration of about 0.005 mg/kg , or at a concentration less than 0.005 mg/kg .

[0030] The disclosure additionally provides any of the above-described B7-H3 x CD3 bi-specific monovalent Fc diabodies for use as a pharmaceutical.

[0030a] In a fifth aspect, there is provided a pharmaceutical composition comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of the first aspect and a pharmaceutically acceptable carrier.

[0030b] In a sixth aspect, there is provided a pharmaceutical composition comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of the second aspect and a pharmaceutically acceptable carrier.

[0030c] In a seventh aspect, there is provided a pharmaceutical composition comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of the third aspect and a pharmaceutically acceptable carrier.

[0030d] In an eighth aspect, there is provided a pharmaceutical composition comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of the fourth aspect and a pharmaceutically acceptable carrier.

[0031] The disclosure additionally provides any of the above-described B7-H3 x CD3 bi-specific monovalent Fc diabodies for use in the treatment of a disease or condition associated with or characterized by the expression of B7-H3, or in a method of treating a disease or

condition characterized by the expression of B7-H3, particularly wherein the disease or condition associated with or characterized by the expression of B7-H3 is cancer, and more particularly, wherein the cancer is selected from the group consisting of: an acute myeloid leukemia, an adrenal gland tumor, an AIDS-associated cancer, an alveolar soft part sarcoma, an astrocytic tumor, bladder cancer, bone cancer, a brain and spinal cord cancer, a metastatic brain tumor, a breast cancer, a carotid body tumors, a cervical cancer, a chondrosarcoma, a chordoma, a chromophobe renal cell carcinoma, a clear cell carcinoma, a colon cancer, a colorectal cancer, a cutaneous benign fibrous histiocytoma, a desmoplastic small round cell tumor, an ependymoma, a Ewing's tumor, an extraskkeletal myxoid chondrosarcoma, a fibrogenesis imperfecta ossium, a fibrous dysplasia of the bone, a gallbladder or bile duct cancer, gastric cancer, a gestational trophoblastic disease, a germ cell tumor, a head and neck cancer, hepatocellular carcinoma, a glioblastoma, an islet cell tumor, a Kaposi's Sarcoma, a kidney cancer, a leukemia, a lipoma/benign lipomatous tumor, a liposarcoma/malignant lipomatous tumor, a liver cancer, a lymphoma, a lung cancer, a medulloblastoma, a melanoma, a meningioma, a malignant mesothelioma, a multiple endocrine neoplasia, a multiple myeloma, a myelodysplastic syndrome, a neuroblastoma, a neuroendocrine tumors, a non-small cell lung cancer, an ovarian cancer, a pancreatic cancer, a pharyngeal cancer, a papillary thyroid carcinoma, a parathyroid tumor, a pediatric cancer, a peripheral nerve sheath tumor, a phaeochromocytoma, a pituitary tumor, a prostate cancer, a posterior uveal melanoma, a rare hematologic disorder, a renal cell carcinoma, a renal metastatic cancer, a rhabdoid tumor, a rhabdomyosarcoma, a sarcoma, a skin cancer, a soft-tissue sarcoma, a squamous cell cancer, a stomach cancer, a synovial sarcoma, a testicular cancer, a thymic carcinoma, a thymoma, a thyroid metastatic cancer, and a uterine cancer.

[0031a] In a ninth aspect, there is provided the B7-H3 x CD3 bispecific monovalent Fc diabody of the first aspect, or the pharmaceutical composition of the fifth aspect, for use in treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.

[0031b] In a tenth aspect, there is provided use of the B7-H3 x CD3 bispecific monovalent Fc diabody of the first aspect, or the pharmaceutical composition of the fifth aspect, in the manufacture of a medicament for treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.

[0031c] In an eleventh aspect, there is provided the B7-H3 x CD3 bispecific monovalent Fc diabody of the second aspect, or the pharmaceutical composition of the sixth aspect, for use in treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.

[0031d] In a twelfth aspect, there is provided use of the B7-H3 x CD3 bispecific monovalent Fc diabody of the second aspect, or the pharmaceutical composition of the sixth aspect, in the manufacture of a medicament for treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.

[0031e] In a thirteenth aspect, there is provided the B7-H3 x CD3 bispecific monovalent Fc diabody of the third aspect, or the pharmaceutical composition of the seventh aspect, for use in treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.

[0031f] In a fourteenth aspect, there is provided use of the B7-H3 x CD3 bispecific monovalent Fc diabody of the third aspect, or the pharmaceutical composition of the seventh aspect, in the manufacture of a medicament for treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.

[0031g] In a fifteenth aspect, there is provided the B7-H3 x CD3 bispecific monovalent Fc diabody of the fourth aspect, or the pharmaceutical composition of the eighth aspect, for use in treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.

[0031h] In a sixteenth aspect, there is provided use of the B7-H3 x CD3 bispecific monovalent Fc diabody of the fourth aspect, or the pharmaceutical composition of the eighth aspect, in the manufacture of a medicament for treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.

[0031i] In a seventeenth aspect, there is provided a kit comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of the first aspect and a pharmaceutically acceptable carrier.

[0031j] In an eighteenth aspect, there is provided a kit comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of the second aspect and a pharmaceutically acceptable carrier.

[0031k] In a nineteenth aspect, there is provided a kit comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of the third aspect and a pharmaceutically acceptable carrier.

[0031l] In a twentieth aspect, there is provided a kit comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of the fourth aspect and a pharmaceutically acceptable carrier.

Brief Description Of The Drawings

[0032] **Figure 1** illustrates the structure of a covalently associated bispecific monovalent diabody composed of two polypeptide chains, which does not comprise an Fc Region. The polypeptide chains are covalently associated to one another via disulfide bonds that form between cysteine (“C”) residues.

[0033] **Figures 2A and 2B** illustrate the structures of two versions of the first, second and third polypeptide chains of a three chain bispecific monovalent Fc diabody of the present invention (Version 1, **Figure 2A**; Version 2, **Figure 2B**). The polypeptide chains are

What Is Claimed Is:

- Claim 1. A B7-H3 x CD3 bispecific monovalent Fc diabody capable of specific binding to B7-H3 and to CD3, wherein the diabody comprises a first, a second and a third polypeptide chain, wherein said polypeptide chains form a covalently bonded complex, and wherein:
- (A) said first polypeptide chain comprises the amino acid sequence of **SEQ ID NO:53**;
 - (B) said second polypeptide chain comprises the amino acid sequence of **SEQ ID NO:55**; and
 - (C) said third polypeptide chain comprises the amino acid sequence of **SEQ ID NO:57**.
- Claim 2. A pharmaceutical composition comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 1 and a pharmaceutically acceptable carrier.
- Claim 3. The pharmaceutical composition of claim 2, wherein said pharmaceutically acceptable carrier is a sterile liquid.
- Claim 4. The pharmaceutical composition of claim 3, wherein said pharmaceutical composition is for intravenous administration.
- Claim 5. The B7-H3 x CD3 bispecific monovalent Fc diabody of claim 1, or the pharmaceutical composition of any one of claims 2-4, for use in treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.
- Claim 6. Use of the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 1, or the pharmaceutical composition of any one of claims 2-4, in the manufacture of a medicament for treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.
- Claim 7. The B7-H3 x CD3 bispecific monovalent Fc diabody or the pharmaceutical composition of claim 5, or the use of claim 6, wherein said cancer is selected from the group consisting of: an acute myeloid leukemia, an adrenal gland tumor, an AIDS-associated cancer, an alveolar soft part sarcoma, an astrocytic tumor, bladder cancer, bone cancer, a brain and spinal cord cancer, a metastatic brain tumor, a breast cancer, a carotid body tumors, a cervical cancer, a chondrosarcoma, a chordoma, a chromophobe renal cell carcinoma, a clear cell carcinoma, a colon cancer, a colorectal cancer, a desmoplastic small round cell tumor, an ependymoma, a Ewing's tumor, an extraskeletal myxoid chondrosarcoma, a gallbladder or bile duct cancer, gastric cancer, a gestational trophoblastic disease, a germ cell tumor, a head and neck cancer, hepatocellular carcinoma, a glioblastoma, an islet cell tumor, a Kaposi's Sarcoma, a kidney cancer, a leukemia, a

liposarcoma/malignant lipomatous tumor, a liver cancer, a lymphoma, a lung cancer, a medulloblastoma, a melanoma, a meningioma, a malignant mesothelioma, a multiple endocrine neoplasia, a multiple myeloma, a myelodysplastic syndrome, a neuroblastoma, a neuroendocrine tumors, a non-small cell lung cancer, an ovarian cancer, a pancreatic cancer, a pharyngeal cancer, a papillary thyroid carcinoma, a parathyroid tumor, a pediatric cancer, a peripheral nerve sheath tumor, a pheochromocytoma, a pituitary tumor, a prostate cancer, a posterior uveal melanoma, a renal cell carcinoma, a renal metastatic cancer, a rhabdoid tumor, a rhabdomyosarcoma, a sarcoma, a skin cancer, a soft-tissue sarcoma, a squamous cell cancer, a stomach cancer, a synovial sarcoma, a testicular cancer, a thymic carcinoma, a thymoma, a thyroid metastatic cancer, and a uterine cancer.

- Claim 8. The B7-H3 x CD3 bispecific monovalent Fc diabody, or the pharmaceutical composition, or the use of claim 7, wherein said cancer is selected from the group consisting of: bladder cancer, breast cancer, colorectal cancer, gastric cancer, glioblastoma, kidney cancer, lung cancer, melanoma, neuroblastoma, ovarian cancer, pancreatic cancer, pharyngeal cancer, prostate cancer, renal cell carcinoma, rhabdomyosarcoma, and squamous cell cancer of the head and neck (SCCHN).
- Claim 9. A kit comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 1 and a pharmaceutically acceptable carrier.
- Claim 10. The kit of claim 9, further comprising one or more prophylactic or therapeutic agents.
- Claim 11. A B7-H3 x CD3 bispecific monovalent Fc diabody capable of specific binding to B7-H3 and to CD3, wherein the diabody comprises a first, a second and a third polypeptide chain, wherein said polypeptide chains form a covalently bonded complex, and wherein:
- (A) said first polypeptide chain comprises the amino acid sequence of **SEQ ID NO:59**;
 - (B) said second polypeptide chain comprises the amino acid sequence of **SEQ ID NO:60**; and
 - (C) said third polypeptide chain comprises the amino acid sequence of **SEQ ID NO:57**.
- Claim 12. A pharmaceutical composition comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 11 and a pharmaceutically acceptable carrier.

- Claim 13. The pharmaceutical composition of claim 12, wherein said pharmaceutically acceptable carrier is a sterile liquid.
- Claim 14. The pharmaceutical composition of claim 13, wherein said pharmaceutical composition is for intravenous administration.
- Claim 15. The B7-H3 x CD3 bispecific monovalent Fc diabody of claim 11, or the pharmaceutical composition of any one of claims 12-14, for use in treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.
- Claim 16. Use of the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 11, or the pharmaceutical composition of any one of claims 12-14, in the manufacture of a medicament for treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.
- Claim 17. The B7-H3 x CD3 bispecific monovalent Fc diabody or the pharmaceutical composition of claim 15, or the use of claim 16, wherein said cancer is selected from the group consisting of: an acute myeloid leukemia, an adrenal gland tumor, an AIDS-associated cancer, an alveolar soft part sarcoma, an astrocytic tumor, bladder cancer, bone cancer, a brain and spinal cord cancer, a metastatic brain tumor, a breast cancer, a carotid body tumors, a cervical cancer, a chondrosarcoma, a chordoma, a chromophobe renal cell carcinoma, a clear cell carcinoma, a colon cancer, a colorectal cancer, a desmoplastic small round cell tumor, an ependymoma, a Ewing's tumor, an extraskeletal myxoid chondrosarcoma, a gallbladder or bile duct cancer, gastric cancer, a gestational trophoblastic disease, a germ cell tumor, a head and neck cancer, hepatocellular carcinoma, a glioblastoma, an islet cell tumor, a Kaposi's Sarcoma, a kidney cancer, a leukemia, a liposarcoma/malignant lipomatous tumor, a liver cancer, a lymphoma, a lung cancer, a medulloblastoma, a melanoma, a meningioma, a malignant mesothelioma, a multiple endocrine neoplasia, a multiple myeloma, a myelodysplastic syndrome, a neuroblastoma, a neuroendocrine tumors, a non-small cell lung cancer, an ovarian cancer, a pancreatic cancer, a pharyngeal cancer, a papillary thyroid carcinoma, a parathyroid tumor, a pediatric cancer, a peripheral nerve sheath tumor, a pheochromocytoma, a pituitary tumor, a prostate cancer, a posterior uveal melanoma, a renal cell carcinoma, a renal metastatic cancer, a rhabdoid tumor, a rhabdomyosarcoma, a sarcoma, a skin cancer, a soft-tissue sarcoma, a squamous cell cancer, a stomach cancer, a synovial sarcoma, a testicular cancer, a thymic carcinoma, a thymoma, a thyroid metastatic cancer, and a uterine cancer.

- Claim 18. The B7-H3 x CD3 bispecific monovalent Fc diabody, or the pharmaceutical composition, or the use of claim 17, wherein said cancer is selected from the group consisting of: bladder cancer, breast cancer, colorectal cancer, gastric cancer, glioblastoma, kidney cancer, lung cancer, melanoma, neuroblastoma, ovarian cancer, pancreatic cancer, pharyngeal cancer, prostate cancer, renal cell carcinoma, rhabdomyosarcoma, and squamous cell cancer of the head and neck (SCCHN).
- Claim 19. A kit comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 11 and a pharmaceutically acceptable carrier.
- Claim 20. The kit of claim 19, further comprising one or more prophylactic or therapeutic agents.
- Claim 21. A B7-H3 x CD3 bispecific monovalent Fc diabody capable of specific binding to B7-H3 and to CD3, wherein the diabody comprises a first, a second and a third polypeptide chain, wherein said polypeptide chains form a covalently bonded complex, and wherein:
- (A) said first polypeptide chain comprises the amino acid sequence of **SEQ ID NO:61**;
 - (B) said second polypeptide chain comprises the amino acid sequence of **SEQ ID NO:62**; and
 - (C) said third polypeptide chain comprises the amino acid sequence of **SEQ ID NO:57**.
- Claim 22. A pharmaceutical composition comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 21 and a pharmaceutically acceptable carrier.
- Claim 23. The pharmaceutical composition of claim 22, wherein said pharmaceutically acceptable carrier is a sterile liquid.
- Claim 24. The pharmaceutical composition of claim 23, wherein said pharmaceutical composition is for intravenous administration.
- Claim 25. The B7-H3 x CD3 bispecific monovalent Fc diabody of claim 21, or the pharmaceutical composition of any one of claims 22-24, for use in treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.
- Claim 26. Use of the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 21, or the pharmaceutical composition of any one of claims 22-24, in the manufacture of a medicament for treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.
- Claim 27. The B7-H3 x CD3 bispecific monovalent Fc diabody or the pharmaceutical composition of claim 25, or the use of claim 26, wherein said cancer is selected from the group consisting of: an acute myeloid leukemia, an adrenal gland tumor, an AIDS-associated cancer, an alveolar soft part sarcoma, an astrocytic tumor, bladder cancer, bone cancer, a brain and spinal cord cancer, a metastatic brain tumor, a breast cancer, a carotid body tumors, a cervical cancer, a chondrosarcoma, a chordoma, a chromophobe renal cell carcinoma, a clear cell carcinoma, a colon cancer, a colorectal cancer, a desmoplastic small round cell tumor, an ependymoma, a Ewing's tumor, an extraskeletal myxoid chondrosarcoma,

a gallbladder or bile duct cancer, gastric cancer, a gestational trophoblastic disease, a germ cell tumor, a head and neck cancer, hepatocellular carcinoma, a glioblastoma, an islet cell tumor, a Kaposi's Sarcoma, a kidney cancer, a leukemia, a liposarcoma/malignant lipomatous tumor, a liver cancer, a lymphoma, a lung cancer, a medulloblastoma, a melanoma, a meningioma, a malignant mesothelioma, a multiple endocrine neoplasia, a multiple myeloma, a myelodysplastic syndrome, a neuroblastoma, a neuroendocrine tumors, a non-small cell lung cancer, an ovarian cancer, a pancreatic cancer, a pharyngeal cancer, a papillary thyroid carcinoma, a parathyroid tumor, a pediatric cancer, a peripheral nerve sheath tumor, a pheochromocytoma, a pituitary tumor, a prostate cancer, a posterior uveal melanoma, a renal cell carcinoma, a renal metastatic cancer, a rhabdoid tumor, a rhabdomyosarcoma, a sarcoma, a skin cancer, a soft-tissue sarcoma, a squamous cell cancer, a stomach cancer, a synovial sarcoma, a testicular cancer, a thymic carcinoma, a thymoma, a thyroid metastatic cancer, and a uterine cancer.

- Claim 28. The B7-H3 x CD3 bispecific monovalent Fc diabody, or the pharmaceutical composition, or the use of claim 27, wherein said cancer is selected from the group consisting of: bladder cancer, breast cancer, colorectal cancer, gastric cancer, glioblastoma, kidney cancer, lung cancer, melanoma, neuroblastoma, ovarian cancer, pancreatic cancer, pharyngeal cancer, prostate cancer, renal cell carcinoma, rhabdomyosarcoma, and squamous cell cancer of the head and neck (SCCHN).
- Claim 29. A kit comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 21 and a pharmaceutically acceptable carrier.
- Claim 30. The kit of claim 29, further comprising one or more prophylactic or therapeutic agents.
- Claim 31. A B7-H3 x CD3 bispecific monovalent Fc diabody capable of specific binding to B7-H3 and to CD3, wherein the diabody comprises a first, a second and a third polypeptide chain, wherein said polypeptide chains form a covalently bonded complex, and wherein:
- (A) said first polypeptide chain comprises the amino acid sequence of **SEQ ID NO:63**;
 - (B) said second polypeptide chain comprises the amino acid sequence of **SEQ ID NO:64**; and
 - (C) said third polypeptide chain comprises the amino acid sequence of **SEQ ID NO:57**.

- Claim 32. A pharmaceutical composition comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 31 and a pharmaceutically acceptable carrier.
- Claim 33. The pharmaceutical composition of claim 32, wherein said pharmaceutically acceptable carrier is a sterile liquid.
- Claim 34. The pharmaceutical composition of claim 33, wherein said pharmaceutical composition is for intravenous administration.
- Claim 35. The B7-H3 x CD3 bispecific monovalent Fc diabody of claim 31, or the pharmaceutical composition of any one of claims 32-34, for use in treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.
- Claim 36. Use of the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 31, or the pharmaceutical composition of any one of claims 32-34, in the manufacture of a medicament for treating a disease or condition associated with or characterized by the expression of B7-H3, wherein said disease or condition associated with or characterized by the expression of B7-H3 is cancer.
- Claim 37. The B7-H3 x CD3 bispecific monovalent Fc diabody or the pharmaceutical composition of claim 35, or the use of claim 36, wherein said cancer is selected from the group consisting of: an acute myeloid leukemia, an adrenal gland tumor, an AIDS-associated cancer, an alveolar soft part sarcoma, an astrocytic tumor, bladder cancer, bone cancer, a brain and spinal cord cancer, a metastatic brain tumor, a breast cancer, a carotid body tumors, a cervical cancer, a chondrosarcoma, a chordoma, a chromophobe renal cell carcinoma, a clear cell carcinoma, a colon cancer, a colorectal cancer, a desmoplastic small round cell tumor, an ependymoma, a Ewing's tumor, an extraskeletal myxoid chondrosarcoma, a gallbladder or bile duct cancer, gastric cancer, a gestational trophoblastic disease, a germ cell tumor, a head and neck cancer, hepatocellular carcinoma, a glioblastoma, an islet cell tumor, a Kaposi's Sarcoma, a kidney cancer, a leukemia, a liposarcoma/malignant lipomatous tumor, a liver cancer, a lymphoma, a lung cancer, a medulloblastoma, a melanoma, a meningioma, a malignant mesothelioma, a multiple endocrine neoplasia, a multiple myeloma, a myelodysplastic syndrome, a neuroblastoma, a neuroendocrine tumors, a non-small cell lung cancer, an ovarian cancer, a pancreatic cancer, a pharyngeal cancer, a papillary thyroid carcinoma, a parathyroid tumor, a pediatric cancer, a peripheral nerve sheath tumor, a pheochromocytoma, a pituitary tumor, a prostate cancer, a posterior uveal melanoma, a renal cell carcinoma, a renal metastatic cancer, a rhabdoid tumor, a rhabdomyosarcoma, a sarcoma, a skin cancer, a soft-tissue sarcoma, a squamous cell cancer, a stomach cancer, a synovial sarcoma, a testicular cancer, a thymic carcinoma, a thymoma, a thyroid metastatic cancer, and a uterine cancer.

- Claim 38. The B7-H3 x CD3 bispecific monovalent Fc diabody, or the pharmaceutical composition, or the use of claim 37, wherein said cancer is selected from the group consisting of: bladder cancer, breast cancer, colorectal cancer, gastric cancer, glioblastoma, kidney cancer, lung cancer, melanoma, neuroblastoma, ovarian cancer, pancreatic cancer, pharyngeal cancer, prostate cancer, renal cell carcinoma, rhabdomyosarcoma, and squamous cell cancer of the head and neck (SCCHN).
- Claim 39. A kit comprising the B7-H3 x CD3 bispecific monovalent Fc diabody of claim 31 and a pharmaceutically acceptable carrier.
- Claim 40. The kit of claim 39, further comprising one or more prophylactic or therapeutic agents.