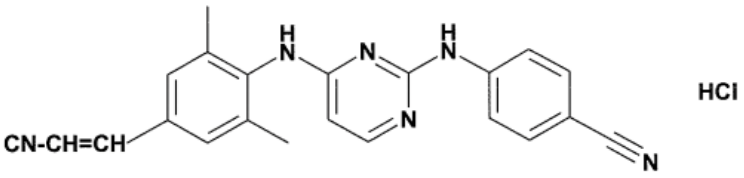
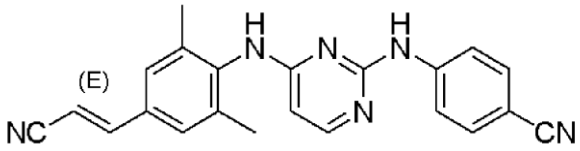
Claims

1. A method for preventing growth of and/or treating a cancerous tumor and/or delaying onset of cancer from tumor-initiating cells, the method comprising:

administering a composition comprising an effective amount of a compound of Formula (I) or Formula (II):



(I)



(II) ,

or any pharmaceutically acceptable salt thereof, to a subject in need thereof, wherein the effective amount of said compound in the composition is from 1 mg to 25 mg per day.

2. The method of claim 1, wherein the cancerous tumor or cancer comprises a mastocytoma or a mast cell tumor, an ovarian cancer, a non-small cell lung cancer, small cell lung cancer, hepatocarcinoma, melanoma, retinoblastoma, breast tumor, colorectal carcinoma, leukemia, lymphoma, acute lymphoblastic leukemia (ALL) or acute lymphoid leukemia, acute myeloid leukemia (AML), a histiocytic sarcoma, a brain tumor, an astrocytoma, a glioblastoma, a neuroma, a neuroblastoma, a colon carcinoma, cervical carcinoma, sarcoma, prostate tumor, bladder tumor, tumor of the reticuloendothelial tissues, Wilm's tumor, ovarian carcinoma, a

bone cancer, an osteosarcoma, a renal cancer, or head and neck cancer, oral cancer, a laryngeal cancer, or an oropharyngeal cancer.

3. The method of claim 2, wherein the cancerous tumor or cancer comprises neuroblastoma.

4. The method of claim 1, wherein said subject is a human comprising adult, juvenile, children or infants.

5. The method of claim 1, wherein the composition is administered at least once daily.

6. The method of claim 1, wherein the administering a composition of Formula (I) is in combination with one or more chemotherapeutic agents, biological agents and/or anticancer agents, to a subject in need thereof.

7. The method of claim 6 wherein the one or more chemotherapeutic agents comprises one or more alkylating agents, anti-metabolites, antitumor antibiotics, topoisomerase inhibitors, mitotic inhibitors, steroids, and/or any mixtures thereof; and

the one or more biological agents comprises one or more vaccines, cytokines, antibodies, protein and peptide drugs and/or any mixtures thereof.

8. The method of claim 7, wherein said alkylating agents are one or more selected from cyclophosphamide, melphalan, temozolomide, carboplatin, cisplatin, and/or oxaliplatin.

9. The method of claim 7, wherein said anti-metabolites are one or more selected from 5-fluorouracil, 6-mercaptopurine, cytarabine, gemcitabine, and/or methotrexate.

10. The method of claim 7, wherein said antitumor antibiotics are one or more selected from actinomycin-D, bleomycin, daunorubicin, and/or doxorubicin.

11. The method of claim 7, wherein said topoisomerase inhibitors are one or more selected from etoposide, irinotecan, teniposide, and/or topotecan.

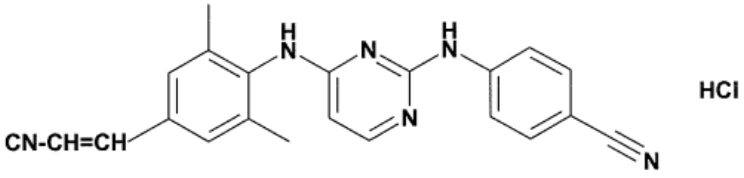
12. The method of claim 7, wherein said mitotic inhibitors are one or more selected from docetaxel, estramustine, paclitaxel, and/or vinblastine.

13. The method of claim 7, wherein said steroids are one or more selected from prednisone, methylprednisolone, and/or dexamethasone.

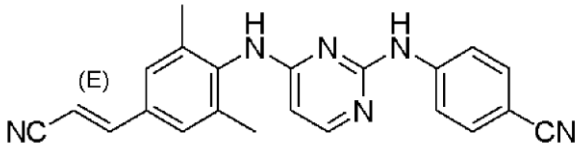
14. The method of claim 7, wherein said antibodies are selected from Hu3F8, hu14.18K322A, Hu14.18-IL-2, dinutuximab or any combination thereof.

15. A composition for preventing growth of and/or treating a cancerous tumor and/or delaying onset of cancer from tumor-initiating cells, the composition comprising:

an effective amount of a compound of Formula (I) or Formula (II):



(I)



(II) ;

or any pharmaceutically acceptable salt thereof, the composition further including one or more antitumor antibiotics selected from actinomycin-D, bleomycin, daunorubicin, and/or doxorubicin;

topoisomerase inhibitors selected from etoposide, irinotecan, teniposide, and/or topotecan;

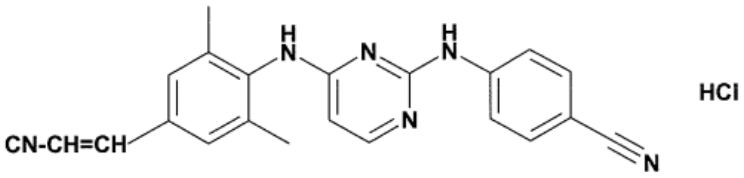
mitotic inhibitors selected from docetaxel, estramustine, paclitaxel, and/or vinblastine;

steroids selected from prednisone, methylprednisolone, and/or dexamethasone; or antibodies selected from Hu3F8, hu14.18K322A, Hu14.18-IL-2, dinutuximab or any combination thereof.

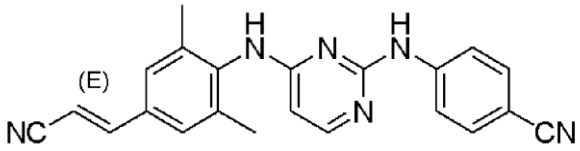
16. The composition of claim 15, wherein said composition is formulated into one or more of the following administrative forms: a parenteral formulation, an aqueous solution, a liposome, an injectable solution, an injectable suspension, an intravenous solution, an intravenous suspension/nanosuspension, a tablet, a pill, a lozenge, a capsule, a caplet, a patch, a spray, an inhalant, a powder, a freeze-dried powder, a patch, a gel, a geltab, a suspension, a nanosuspension, a microparticle, a nanoparticle, a nanoliposome, a microgel, a pellet, a suppository, an oral suspension, an oral disintegrating tablet, an oral dispersible tablet, an oral disintegrating film, a microemulsion, a nanoemulsion and a self-emulsifying drug delivery system and/or any combination thereof.

17. A method for reducing the frequency or amount of a chemotherapeutic agent needed to treat a cancerous tumor and/or delay progression of cancer from tumor-initiating cells, the method comprising:

administering a composition comprising an effective amount of a compound of Formula (I) or Formula (II):



(I)



(II) ,

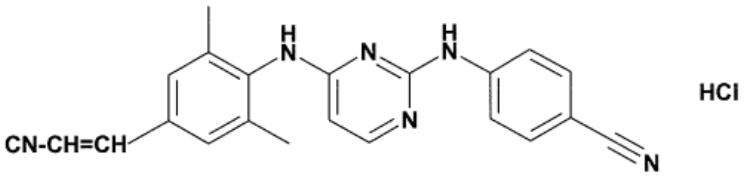
or any pharmaceutically acceptable salt thereof, in combination with one or more of chemotherapeutic agents, to a subject in need thereof,

the one or more of the chemotherapeutic agents being selected from alkylating agents, anti-metabolites, antitumor antibiotics, topoisomerase inhibitors, mitotic inhibitors, steroids and/or any mixtures thereof;

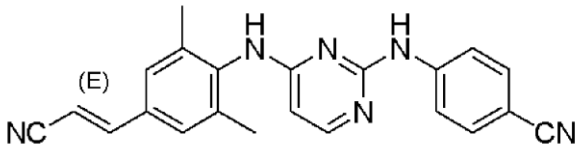
wherein the frequency or amount of the chemotherapeutic agent administered is approximately up to 75 to 90 percent less than a standard protocol without administration of the composition comprising an effective amount of the compound of Formula (I) or Formula (II).

18. A method for preventing growth of and/or treating a cancerous tumor and/or delaying onset of cancer from tumor-initiating cells, the method comprising:

administering a composition comprising an effective amount of a compound of Formula (I) or Formula (II):



(I)



(II) ,

or any pharmaceutically acceptable salt thereof, to a subject in need thereof,

wherein the administering a composition of Formula (I) or Formula (II) is in combination with one or more chemotherapeutic agents or biological agents,

wherein the one or more chemotherapeutic agents are selected from (i) antitumor antibiotics selected from actinomycin-D, bleomycin, daunorubicin, and/or doxorubicin; (ii) topoisomerase inhibitors selected from etoposide, irinotecan, teniposide, and/or topotecan; (iii) mitotic inhibitors selected from docetaxel, estramustine, paclitaxel, and/or vinblastine; (iv) steroids selected from prednisone, methylprednisolone, and/or dexamethasone; and/or (v) any mixtures thereof; and

wherein the one or more biological agents are selected from antibodies selected from Hu3F8, hu14.18K322A, Hu14.18-IL-2, dinutuximab or any combination thereof.

19. The method of claim 18, wherein the cancerous tumor or cancer comprises a mastocytoma or a mast cell tumor, an ovarian cancer, a non-small cell lung cancer, small cell lung cancer, hepatocarcinoma, melanoma, retinoblastoma, breast tumor, colorectal carcinoma, leukemia, lymphoma, acute lymphoblastic leukemia (ALL) or acute lymphoid leukemia, acute myeloid leukemia (AML), a histiocytic sarcoma, a brain tumor, an astrocytoma, a glioblastoma, a neuroma, a neuroblastoma, a colon carcinoma, cervical carcinoma, sarcoma, prostate tumor, bladder tumor, tumor of the reticuloendothelial tissues, Wilm's tumor, ovarian carcinoma, a bone cancer, an osteosarcoma, a renal cancer, or head and neck cancer, oral cancer, a laryngeal cancer, or an oropharyngeal cancer.

20. The method of claim 19, wherein the cancerous tumor or cancer comprises neuroblastoma.

21. The method of claim 18, wherein said subject is a human comprising adult, juvenile, children or infants.

22. The method of claim 18, wherein the effective amount of the compound in the composition is from 0.1 mg to 1000 mg per day.