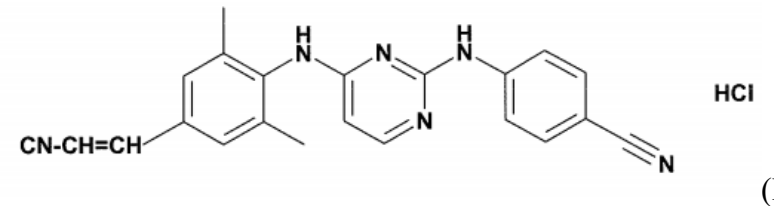
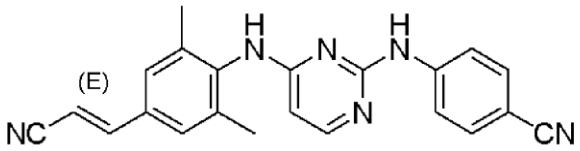
Claims

1. Use of a compound of Formula (I) or Formula (II), or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament to treat or prevent growth of a cancerous tumor and/or delay onset of cancer from tumor-initiating cells for a subject in need thereof,



(I)



(II) ,

wherein said subject is a human comprising adult, juvenile, children or infants;wherein the effective amount of said compound in the medicament is from 60-160 mg per day; or

wherein the effective amount of said compound in the medicament is 400 mg per day.

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

4. The use of claim 1, wherein said medicament further includes one or more chemotherapeutic agents, biological agents and/or anticancer agents.

5. The use of claim 4 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.

6. The use of claim 5, wherein said alkylating agents are one or more selected from cyclophosphamide, melphalan, temozolomide, carboplatin, cisplatin, and/or oxaliplatin.

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

8. The use of claim 5, wherein said antitumor antibiotics are one or more selected from actinomycin-D, bleomycin, daunorubicin, and/or doxorubicin.

9. The use of claim 5, wherein said topoisomerase inhibitors are one or more selected from etoposide, irinotecan, teniposide, and/or topotecan.

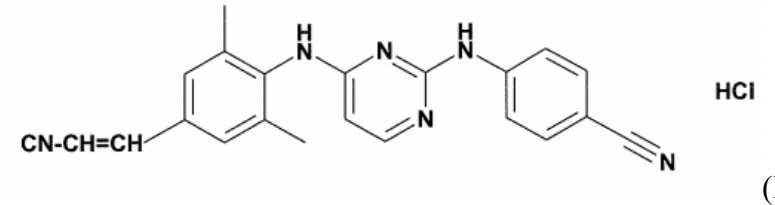
10. The use of claim 5, wherein said mitotic inhibitors are one or more selected from docetaxel, estramustine, paclitaxel, and/or vinblastine.

11. The use of claim 5, wherein said steroids are one or more selected from prednisone, methylprednisolone, and/or dexamethasone.

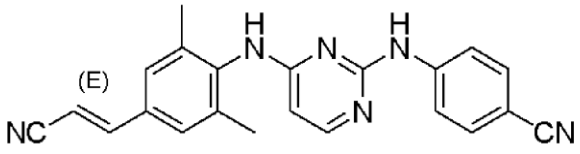
12. The use of claim 5, wherein said antibodies are selected from Hu3F8, hu14.18K322A, Hu14.18-IL-2, dinutuximab or any combination thereof.

13. 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;

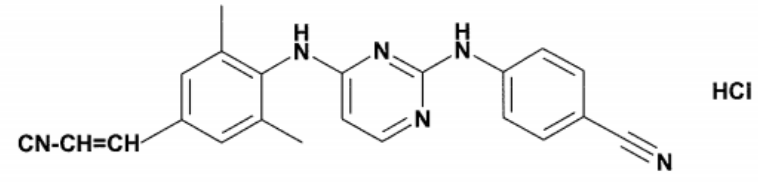
topoisomerase inhibitors selected from etoposide, irinotecan, teniposide, and/or topotecan;

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

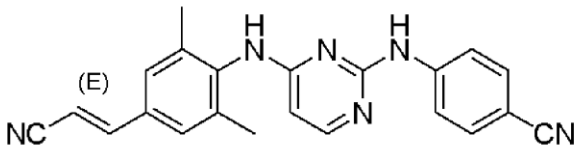
steroids selected from prednisone, methylprednisolone, and/or dexamethasone; or antibodies selected from Hu3F8, hu14.18K322A, Hu14.18-IL-2, dinutuximab or any combination thereof;

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.

14. Use of a compound of Formula (I) or Formula (II) or any pharmaceutically acceptable salt thereof, in combination with one or more of chemotherapeutic agents, in the manufacture of a medicament to reduce the frequency or amount of a chemotherapeutic agent needed to treat a cancerous tumor and/or delay progression of cancer from tumor-initiating cells for a subject in need thereof:



(I)

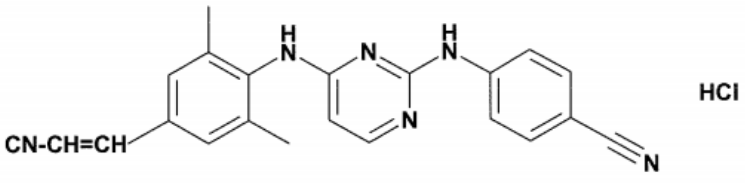


(II) ,

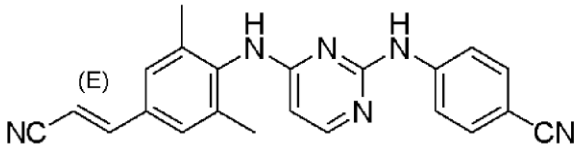
the one or more of the chemotherapeutic agents being selected from alkylating agents, anti-metabolites, antitumor antibiotics, topoisomerase inhibitors, mitotic inhibitors, steroids and/or any mixtures thereof;

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).

15. Use of a compound of Formula (I) or Formula (II), or any pharmaceutically acceptable salt thereof, in the manufacture of a medicament to prevent growth of and/or treat a cancerous tumor and/or delay onset of cancer from tumor-initiating cells:



(I)



(II) ,

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;

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 and neuroblastoma;

wherein said subject is a human comprising adult, juvenile, children or infants; and

wherein the effective amount of the compound in the composition is from 0.1 mg to 1000 mg per day.