

WHAT IS CLAIMED:

1. An intratumor injectable formulation comprising a basic chemotherapeutic drug selected from the group consisting of an anthracycline base, a vinca alkaloid base, eribulin base and an alkylating agent base and a pharmaceutically acceptable biocompatible carrier for injection of the drug selected from the group consisting of PEG, an oleic acid, an alcohol, a glycerin, a median chain triglyceride, a vegetable oil, and mixtures thereof, wherein the intratumor injectable formulation is a solution, suspension or water in oil emulsion.
2. The intratumor injectable formulation of claim 1, wherein the pharmaceutically acceptable biocompatible carrier for injection is an organic liquid selected from the group consisting of a PEG of molecular weight of 200 to 400, a median chain triglyceride, oleic acid, glycerol, a liquid alcohol comprising ethanol and benzyl alcohol, and mixtures thereof, such that the formulation is a solution or suspension.
3. The intratumor injectable formulation of claim 1, wherein the basic chemotherapeutic drug is a desalinated salt form of a chemotherapeutic drug, wherein the biocompatible carrier is selected from the group consisting of a PEG of molecular weight of 200 to 400, a median chain triglyceride, oleic acid, glycerol, a liquid alcohol comprising ethanol and benzyl alcohol, and combinations thereof, wherein the formulation further comprises water in an amount of less than 15% of the total volume of the injectable formulation and a salt selected from the group consisting of sulfate, chloride, mesylate and mixtures thereof, such that the formulation is an water in oil emulsion.
4. The intratumor injectable formulation of claim 1, wherein the vinca alkaloid base is selected from the group consisting of vinblastine, vincristine, vindesine, and mixtures thereof; wherein the anthracycline base is selected from the group consisting of doxorubicin, epirubicin, daunorubicin, mitoxantrone, idarubicin, amrubicin, aclarubicin, valrubicin, and mixtures thereof; and wherein the alkylating agent base is selected from the group consisting of bendamustine, mechlorethamine, procarbazine, and mixtures thereof.
5. The intratumor injectable formulation of claim 1, wherein the injectable formulation is an emulsion comprising the basic chemotherapeutic agent, the biocompatible carrier, an alcohol comprised of ethanol or benzyl alcohol, sodium or potassium chloride, a buffer comprised of an organic acid and wherein the organic acid is selected from the group consisting of acetic acid, malic acid, fumaric acid, tartaric acid, succinic acid, maleic acid, citric acid, ascorbic acid, and mixtures thereof, and wherein the water is less than 15% of the injectable formulation and the amount of organic solvent is more than 85% of the volume of the emulsion.
6. The intratumor injectable formulation of claim 1, wherein the injectable formulation is a water in

oil emulsion comprising an anthracycline base selected from the group consisting of doxorubicin base, epirubicin base, daunorubicin base, amrubicin base and mitoxantrone base, an oleic acid, glycerol, acetic acid, less than 15% of water by volume of the emulsion and an alcohol, wherein the alcohol is selected from the group consisting of ethanol, benzyl alcohol or combinations thereof.

7. The intratumor injectable formulation of claim 1, wherein the formulation is a water in oil emulsion comprising daunorubicin base, oleic acid, ethanol, acetic acid, sodium or potassium chloride and from about 4% to about 10% of water by volume of the emulsion.

8. The intratumor injectable formulation of claim 1, wherein the formulation is a water in oil emulsion comprising amrubicin base, oleic acid, ethanol, acetic acid, sodium or potassium chloride and from about 4% to about 10% of water by volume of the emulsion.

9. The intratumor injectable formulation of claim 1, wherein the formulation is a water in oil emulsion comprising mitoxantrone base, oleic acid, glycerol, ethanol, acetic acid, sodium or potassium chloride and from about 2% to about 10% of water by volume of the emulsion.

10. The intratumor injectable formulation of claim 1, wherein the formulation comprises mitoxantrone base, ethanol and acetic acid and further includes either oleic acid or glycerol, wherein the formulation is a solution or a suspension.

11. The intratumor injectable formulation of claim 1, wherein the formulation is a water in oil emulsion comprising doxorubicin base, oleic acid, ethanol, acetic acid, NACL and from about 4% to about 15% of water by volume of the emulsion.

12. The intratumor injectable formulation of claim 1, wherein the formulation is a water in oil emulsion comprising the basic chemotherapeutic agent, oleic acid, an alcohol, acetic acid, sulfate or chloride, and from about 4% to about 15% of water by volume of the emulsion, wherein the basic chemotherapeutic agent selected from the group consisting of daunorubicin base, epirubicin base, doxorubicin base, mitoxantrone base and amrubicin base.

13. The intratumor injectable formulation of claim 1, wherein the basic chemotherapeutic drug is selected from the group consisting of a vincristine base, a vinblastine base and a vindesine base wherein the biocompatible carrier is a mixture of an alcohol comprising ethanol or benzyl alcohol and a median chain triglyceride, glycerol or oleic acid, and wherein the formulation further comprises acetic acid, sulfate or chloride salt and a small amount of water, such that the formulation is a water in oil emulsion containing from about 0.5% to about 5% of water by volume of the emulsion.

14. The intratumor injectable formulation of claim 1, wherein the basic chemotherapeutic drug comprises bendamustine base and the pharmaceutically acceptable biocompatible carrier is a mixture selected from the group consisting of ethanol mixed with a PEG of molecular weight from about 200

to 400 or oleic acid mixed with acetic acid, such that the formulation is a solution or suspension

15. The intratumor injectable formulation of claim 1, wherein the basic chemotherapeutic drug formulation is a water in oil emulsion comprises bendamustine base and wherein the pharmaceutically acceptable biocompatible carrier is a mixture of oleic acid and an ethanol, the formulation further comprises a water phase of acetic acid, sodium or potassium chloride and from about 2% to about 10% of water by volume of the emulsion.

16. The intratumor injectable formulation of claim 1, wherein the basic chemotherapeutic drug formulation is a water in oil emulsion comprises bendamustine base and wherein the pharmaceutically acceptable biocompatible carrier is a mixture of glycerol and an ethanol, the formulation further comprising a water phase of acetic acid, sodium or potassium chloride and a small amount of water from about 2% to about 10% of water by volume of the emulsion.

17. The intratumor injectable formulation of claim 1, wherein the formulation is a water in oil emulsion comprising bendamustine base dissolved in a mixture of a PEG of molecular weight of 200 to 400 and an ethanol and wherein the emulsion further comprises a water phase of acetic acid, sodium or potassium chloride and from about 2% to about 10% of water by volume of the emulsion.

18. The intratumor injectable formulation of claim 1, wherein the basic chemotherapeutic drug comprises mechlorethamine base and wherein the pharmaceutically acceptable biocompatible carrier is a mixture of a median chain triglyceride and ethanol, the formulation further comprising acetic acid, and less than about 1% of water by volume of the formulation.

19. The intratumor injectable formulation of claim 1, wherein the basic chemotherapeutic drug comprises mechlorethamine base and the pharmaceutically acceptable biocompatible carrier is a mixture of ethanol with a median chain triglyceride, the formulation further comprising acetic acid, sodium or potassium chloride and less than about 10% of water by volume of the formulation, such that the formulation is an emulsion.

20. The intratumor injectable formulation of claim 1, wherein the basic chemotherapeutic drug is eribulin base, wherein the biocompatible carrier is a mixture of an alcohol comprising ethanol or benzyl alcohol and a median chain triglyceride, glycerol, PEG of molecular weight 200 to 400 or oleic acid, and wherein the formulation further comprises acetic acid, sodium mesylate or potassium mesylate and a small amount of water from about 0.5% to about 5% of water by volume of the formulation which is an emulsion.

21. An intratumor injectable formulation kit, comprising a first vial containing a basic chemotherapeutic drug and a second vial containing a pharmaceutically acceptable excipient for delivery of the drug into a tumor, the pharmaceutically acceptable excipient comprising a solvent

selected from the group consisting of a PEG, an oleic acid, glycerin, a median chain triglyceride, an alcohol, a pharmaceutically acceptable diluent, and mixtures thereof, wherein the PEG has a molecular weight from about PEG₂₀₀ to about PEG₄₀₀, and wherein the alcohol is selected from the group consisting of ethanol, propylene glycol, tert-butyl alcohol, benzyl alcohol and combinations thereof; and wherein the basic chemotherapeutic drug is selected from the group consisting of an anthracycline base, a vinca alkaloid base, eribulin base and an alkylating agent base.

22. The intratumor injectable formulation kit of claim 21, wherein the anthracycline base is selected from the group consisting of doxorubicin base, epirubicin base, amrubicin base, daunorubicin base and mitoxantrone base, and wherein the pharmaceutical acceptable excipient comprises a mixture of ethanol and oleic acid, PEG, polysorbate, a median chain triglyceride or glycerol.

23. A method of treating a malignant mass in a mammal, comprising administering the intratumor injectable formulation of claim 1 directly into the malignant mass, wherein the malignant mass is a primary or secondary tumor located in skin, eye, tongue, mouth, thyroid, breast, cervix, uterus, anus, prostate, vagina, bone, urinary bladder, ureter, urethra, penis, testis, epididymis, nasopharynx, liver, kidney, gall bladder, ovary, oviduct, pancreas, metastasis of lymph node, peritoneum metastasis of the abdominal cavity, esophagus, stomach, duodenum, small intestine, large intestine, caecum, rectum, lung, trachea, larynx, brain, a malignant lymphoma or lymph node metastasis, metastatic breast cancer, metastatic Wilms' tumor, Kaposi's sarcoma, metastatic neuroblastoma or a metastatic soft tissue sarcoma.

24. The intratumor injectable formulation of claim 1, wherein the pharmaceutically acceptable biocompatible carrier for injection comprises an alcohol selected from the group consisting of ethanol, benzyl alcohol and combinations thereof.

25. A method of making an intratumor injectable formulation comprising dissolving a basic chemotherapeutic drug selected from the group consisting of an anthracycline base, a vinca alkaloid base, eribulin base or an alkylating agent base in an organic liquid comprising a solvent selected from the group consisting of a PEG of molecular weight of 200 to 400, a median chain triglyceride, oleic acid, glycerol, a liquid alcohol and mixtures thereof.

26. A method of making an intratumor injectable emulsion formulation comprising:

1) the acidic salt of a chemotherapeutic drug selected from the group consisting of a vinca alkaloid salt, an alkylating agent salt, an eribulin salt and an anthracycline salt with an about equal molar amount of a base or a basic salt in an aqueous medium to form a water suspension of a basic chemotherapeutic drug;

2) adding a small amount of an organic acid selected from the group consisting of acetic acid, malic acid, fumaric acid, tartaric acid, succinic acid, maleic acid, citric acid, ascorbic acid and combinations thereof into the suspension to act as a buffer;

3) mixing the resulting desalinated basic chemotherapeutic water mixture with a biocompatible carrier selected from the group consisting of a PEG of molecular weight of 200 to 400, a median chain triglyceride, oleic acid, glycerol, a liquid alcohol comprising ethanol, benzyl alcohol, and mixtures thereof,

wherein the emulsion comprises an amount of water of from about 0.5% to about 15% of the total volume of the injectable formulation.

27. The method of claim 26, wherein the vinca alkaloid salt is selected from the group consisting of vinblastine sulfate, vinblastine chloride, vincristine sulfate, vincristine chloride, vindesine sulfate, and vindesine chloride, wherein the anthracycline salt is selected from the group consisting of doxorubicin hydrochloride, doxorubicin sulfate, doxorubicin citrate, epirubicin hydrochloride, epirubicin sulfate, epirubicin citrate, daunorubicin hydrochloride, daunorubicin sulfate, daunorubicin citrate, mitoxantrone hydrochloride, mitoxantrone sulfate, mitoxantrone citrate, amrubicin hydrochloride, amrubicin sulfate, amrubicin citrate, idarubicin salt, aclarubicin salt and valrubicin salt; and wherein the alkylating agent salt is selected from the group consisting of bendamustine hydrochloride, bendamustine sulfate, mechlorethamine hydrochloride, mechlorethamine sulfate, procarbazine hydrochloride, and procarbazine sulfate.