~~WHAT IS CLAIMED:~~

CLAIMS

1. ~~A pharmaceutical composition, comprising an injectable formulation of a therapeutically effective amount of chemotherapeutic agent dissolved or suspended in a biocompatible carrier, for use in treating a malignant mass in a mammal, wherein the composition is administered directly into the malignant mass.~~

2. ~~The pharmaceutical composition of claim 1, wherein the malignant mass is in a location in the mammal selected from the group consisting of brain, head, eye, nasopharynx, mouth, tongue, neck, thyroid, gastrointestinal system, liver, pancreas, gall bladder, lung, respiratory system, urogenital system, kidney, urinary bladder ,breast, lymphatic system, cardiovascular system, nervous system, skin, thorax, pleural membrane, mesothelioma, lung cancer, muscular skeletal system, abdomen with primary or secondary nature.~~

3. ~~The pharmaceutical composition of claim 2, wherein the malignant mass metastasized from another organ in the mammal.~~

4. ~~The pharmaceutical composition of claim 2, wherein the injectable formulation is administered through a syringe or a needle of a fiberscope.~~

5. ~~The pharmaceutical composition of claim 4, wherein the chemotherapeutic agent is a water insoluble compound selected from the group consisting of a taxane, a podophyllotoxin derivative, or a camptothecin derivative.~~

6. ~~The pharmaceutical composition of claim 5, wherein the water insoluble compound is a taxane selected from the group consisting of paclitaxel and doxetaxel.~~

7. The pharmaceutical composition of claim 5, wherein the water insoluble compound is hydroxycamptothecin.

8. The pharmaceutical composition of claim 5, wherein the biocompatible carrier is selected
from the group consisting of a PEG, a vegetable oil, and a median chain triglyceride.

9. The pharmaceutical composition of claim 1, wherein the chemotherapeutic agent is paclitaxel and the biocompatible carrier is a PEG having a molecular weight of from about PEG 200 to about PEG 400.

10. The pharmaceutical composition of claim 1, wherein the malignant mass is (i) a superficial malignant disease of skin, eye, tongue, mouth, thyroid, breast, cervix, uterus, anus, prostate, vagina, sarcoma of the bone, carcinoma of urethra, penis, testis and epididymis and the chemotherapeutic agent is injected with a syringe directly into the malignant mass without dilution; or

(ii) a cancer of the nasopharynx, and the chemotherapeutic agent is injected into the malignant mass with the syringe or needle through a nasopharyngoscope; or

(iii) a cancer of the liver, kidney and gall bladder, and the chemotherapeutic agent is injected using a syringe through skin into the malignant mass with the assistance of ultrasound, or is injected through a hole made in an abdominal wall of a patient during laparoscopic surgery into the malignant mass; or

(iv) a cancer of the ovary, oviduct, pancreas, metastasis of lymph node or direct peritoneum invasion of the abdominal cavity, lymphoma of the abdomen, and the chemotherapeutic agent is injected with the syringe into the malignant mass through a hole made in the abdominal wall of a patient during laparoscopic surgery; or

(v) a carcinoma or sarcoma of esophagus, stomach, duodenum, small intestine, and the chemotherapeutic agent is injected with the needle into the malignant mass

through an enteroscope or via a long syringe through a hole made in the abdominal wall of a patient during laparoscopic surgery or is injected through a hole made in a thoracic wall of a patient during thorascopic surgery.

(vi) a carcinoma or sarcoma of the large intestine and rectum, and the chemotherapeutic agent is injected with the needle into the malignant mass through colonoscopy or is injected using a syringe through a hole made in the abdominal wall of a patient during laparoscopic surgery; or

(vii) a carcinoma or sarcoma of the lung and trachea, and the chemotherapeutic agent is injected using the needle of a fiber bronchoscope into the malignant mass; or

(viii) a carcinoma of the lung, and the chemotherapeutic agent is injected with the syringe with the use of ultrasound, x-ray, CT scan, or MR scan or is injected through a hole made in the thoracic wall of a patient during thoracoscopic surgery; or

(ix) a carcinoma or sarcoma of the urinary bladder, and the chemotherapeutic agent is injected into the malignant mass with a needle through a cystoscope, or is injected through a hole made in the abdominal wall of a patient during laparoscopic surgery; or

(x) a carcinoma or sarcoma of uterus, and the injectable formulation of chemotherapeutic agent is injected into the malignant mass with a syringe or a needle of a hysteroscope; or is injected through a hole made in the abdominal wall of a patient during laparoscopic surgery; or

(xi) a carcinoma or sarcoma of nasopharynx and larynx, and the chemotherapeutic agent is injected into the malignant mass with a needle through a laryngoscope; or

(xii) a carcinoma of the brain, and the chemotherapeutic agent is injected with a needle of a syringe or a fiberscope into the malignant mass after a hole is drilled in the corresponding bone of a skull with the use of an X-ray, CT scan or MR scan; or

(xiii) a malignant lymphoma or lymph node with metastasis, and the

~~chemotherapeutic agent is injected into the malignant mass using a needle through the skin of a patient or is injected through a hole made in the abdominal wall of a patient during laparoscopic surgery or through a hole made in the thoracic wall of a patient during thoracoscopic surgery.~~

~~11.~~ A stable intratumor injectable formulation of a water insoluble chemotherapeutic agent, ~~comprising~~consisting of a therapeutically effective amount of a chemotherapeutic agent selected from a taxane, a podophyllotoxin derivative, a camptothecin derivative~~, analogues or prodrugs thereof, a pharmaceutically acceptable salt thereof~~, and mixtures thereof in a pharmaceutically acceptable biocompatible carrier for injection ~~consisting of a PEG having a molecular weight from about PEG 200 to about PEG 400,~~ comprising a medium chain triglyceride or a pharmaceutically acceptable vegetable oil, and an optional solvent which when included consists of a non-aqueous solvent, wherein the injectable formulation is stable and suitable for intratumor administration as a solution and is a colorless and transparent non-aqueous solution that does not include cholesterol, a phospholipid, a protein, or surfactant.

~~12.~~ 2. The intratumor injection formulation of claim ~~11~~1, wherein the ~~vegetable oil~~taxane is ~~soybean oil~~paclitaxel.

~~13.~~ 3. The intratumor injection formulation of claim ~~11, wherein the~~ 1, wherein the chemotherapeutic agent is paclitaxel and the pharmaceutically acceptable biocompatible carrier for injection is a medium chain triglyceride is ~~a medium chain triglyceride is~~an esterification product of an acid selected from the group consisting of caproic acid, caprylic acid, capric acid, lauric acid, and mixtures thereof, further comprising a hydroalcoholic solvent.

~~14.~~ 4. The intratumor injectable formulation of claim ~~2~~1, wherein the chemotherapeutic agent is hydroxycamptothecin and the pharmaceutically acceptable biocompatible carrier for injection comprises a medium chain triglyceride.

5. The intratumor injection formulation of claim 1, wherein the taxane is ~~paclitaxel,~~doxetaxel.

6. The intratumor injectable formulation of claim 1, wherein the podophyllotoxin derivative is selected from the group consisting of etoposide, teniposide, and mixtures thereof~~, and the camptothecin derivative is hydroxycamptothecin~~.

~~15.~~ 7. The intratumor injectable formulation of claim 1, wherein the camptothecin derivative is hydroxycamptothecin.

8. An intratumor injectable formulation kit, comprising a first vial containing a ~~crystallized, powdered, or lyophilized~~ water insoluble chemotherapeutic agent selected from a taxane, a podophyllotoxin derivative, a camptothecin derivative, and mixtures thereof, and a second vial containing the pharmaceutically acceptable excipients needed to deliver the chemotherapeutic agent to a tumor, the pharmaceutically acceptable excipients ~~including a PEG having a molecular weight from about PEG 200 to about PEG 400,~~consisting of a pharmaceutically acceptable biocompatible carrier comprising a medium chain triglyceride~~, ethanol, alcohol,~~ or a pharmaceutically acceptable vegetable oil, ~~a polysorbate, a pharmaceutically acceptable diluent,~~ and ~~mixtures of any~~an optional solvent which when included consists of a non-aqueous solvent, wherein the ~~foregoing~~injectable formulation is suitable for intratumor administration as a solution that is stable, colorless, transparent and non-aqueous and does not include cholesterol, a phospholipid, a protein, or surfactant.

9. The intratumor injectable formulation of claim 1, which further comprises a buffer to provide a pH from about 3.5 to about 4.5.

10. The intratumor injectable formulation of claim 9, wherein the buffer comprises citric acid.

11. The formulation of claim 1, wherein the injectable solution is capable of being passed through a 0.22-micron filter.

12. The formulation of claim 9, wherein the chemotherapeutic agent is paclitaxel, the pharmaceutically acceptable biocompatible carrier for injection is a medium chain triglyceride, and the solvent is dehydrated ethanol.

13. The intratumor injectable formulation of claim 8, which further comprises a buffer to provide a pH from about 3.5 to about 4.5.