Claims

What is claimed is:

1. A method of treating cancer in the lung comprising administering to a patient in need thereof a therapeutically effective amount of liposomal annamycin.

2. The method of claim 1, wherein said patient has primary or metastatic cancer in the lung.

3. The method of claim 2, wherein the primary lung cancer is non-small-cell lung carcinoma (NSCLC) or small-cell lung carcinoma (SCLC).

4. The method of claim 3, wherein the primary lung cancer is a non-small-cell lung cancer selected from adenocarcinoma, squamous-cell carcinoma, and large-cell carcinoma.

5. The method of claim 2, wherein said patient has metastatic cancer in the lung.

6. The method of claim 5, wherein the metastatic cancer is a metastasis of a primary cancer selected from bladder cancer, breast cancer, colorectal cancer, head and neck cancer, kidney cancer, melanoma, pancreatic cancer, prostate cancer, and ovarian cancer.

7. The method of claim 5, wherein the metastatic cancer is a metastasis of a sarcoma.

8. The method of claim 5, wherein the metastatic cancer is from a cancer of unknown primary origin.

9. The method of any one of the preceding claims further comprising administering an effective amount of at least one chemotherapeutic agent to the subject.

10. The method of claim 9, wherein the at least one chemotherapeutic agent is selected from actinomycin, afatinib, alectinib, asparaginase, azacitidine, azathioprine, bicalutamide, bleomycin, bortezomib, camptothecin, carboplatin, capecitabine, certinib, cetuximab,cisplatin, chlorambucil, crizotinib, cyclophosphamide, cytarabine, daunorubicin, docetaxel, doxifluridine, doxorubicin, erlotinib, epirubicin, epothilone, etoposide, fludarabine, flutamine, fluorouracil, fostamatinib, gefitinib, gemcitabine,

hydroxyurea, ibrutinib, idarubicin, ifosfamide, imatinib, ipilimumab, irinotecan, lapatinib, letrozole, mechlorethamine, mercaptopurine, methotrexate, mitomycin, mitoxantrone, nilotinib, octreotide, oxaliplatin, paclitaxel, palbociclib, panitumumab, pemetrexed, raltitrexed, selumetinib, sorafenib, sunitinib, tamoxifen, temozolomide, teniposide, tioguanine, topotecan, trastuzumab, tremelimumab, valrubicin, vemurafenib, vinblastine, vincristine, vindesine, vinorelbine, and combinations thereof.

11. The method of claim 9, wherein the at least one chemotherapeutic agent comprises a combination selected from:

cyclophosphamide, doxorubicin, and vincristine;

mitomycin, vindesine and cisplatin;

cisplatin and vinorelbine; and

cisplatin, etoposide and ifosfamide.

12. .The method of any one of claims 1 to 8, further comprising administering an effective amount of at least one immunotherapeutic agent to the subject.

13. The method of any one of the preceding claims, further comprising one or both of resecting the lung cancer and administering radiation therapy.

14. The method of any one of the preceding claims, wherein treating cancer in the lung comprises one or more of the following: (a) increasing survival time of the patient; (b) reducing volume of the primary cancer; (c) retarding growth of the primary cancer; (d) reducing number of metastatic tumors; (e) reducing volume of metastatic tumors; and (f) retarding growth of metastatic tumors.

15. The method of any one of the preceding claims, wherein treating cancer in the lung does not result in annamycin-induced toxicity of the lung of such severity that repeated administration of the annamycin is contraindicated.

16. The method of any one of the preceding claims, wherein treating cancer in the lung does not result in annamycin-induced systemic toxicity of such severity that repeated administration of the annamycin is contraindicated.

17. The method of any one of the preceding claims, wherein said administering is repeated weekly.

18. The method of any one of claims 1 to 16, wherein said administering is repeated every two, three, or four weeks.

19. The method of any one of claims 1 to 18, wherein the liposomal annamycin comprises annamycin, one or more lipids, and one or more non-ionic surfactants.

20. The method of claim 19, wherein the lipids comprise Dimyristoylphosphatidylcholine (DMPC) and dimyristoylphosphatidylglycerol (DMPG).

21. The method of claim 19 or 20, wherein the non-ionic surfactant comprises a polysorbate-type surfactant formed from the ethoxylation of sorbitan followed by the addition of a carboxylic acid.

22. The method of claim 21 wherein the non-ionic surfactant comprises polyoxyethylene sorbitan monolaurate.

23. The method of any one of the preceding claims, wherein the liposomal annamycin is provided as a preliposomal lyophilizate composition that is reconstituted into an aqueous liposome composition through hydration prior to administration.

24. The method of claim 23, wherein the preliposomal annamycin lyophilizate comprises:
1.8 – 2.2 wt % annamycin;
3.0 – 3.4 wt. % Polysorbate 20; and
94.4 - 95.2 wt. % of lipids selected from DMPC and DMPG.

25. The method of claim 24, wherein the DMPC is 65.3 - 67.3 wt. % and the DMPG is 27.1 – 29.9 wt. %.