CLAIMS

What is claimed is:

1. Use of a therapeutically effective amount of liposomal annamycin in the manufacture of a medicament for treating primary or metastatic cancer in the lung in a patient, wherein the primary cancer is non-small cell lung carcinoma or small-cell lung carcinoma, and wherein the metastatic cancer is metastasis of a primary cancer wherein said primary cancer is bladder cancer, breast cancer, colorectal cancer, head and neck cancer, kidney cancer, melanoma, pancreatic cancer, prostate cancer, sarcomas, or ovarian cancer.

2. The use of claim 5, wherein said patient has metastatic cancer in the lung selected from colon cancer, triple negative breast cancer, and Sarcoma.

3. The use of claim 1, wherein the primary lung cancer is non-small-cell lung carcinoma (NSCLC) or small-cell lung carcinoma (SCLC).

4. The use 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 use of claim 1, wherein said patient has metastatic cancer in the lung.

6. The use 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 use of claim 5, wherein the metastatic cancer is a metastasis of a sarcoma.

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

9. The use of any one of the preceding claims, wherein an effective amount of at least one chemotherapeutic agent is to be further administered to the subject.

10. The use 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 use 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 use of any one of claims 1 to 8, wherein an effective amount of at least one immunotherapeutic agent is to be further administered to the subject.

13. The use of any one of the preceding claims, wherein the lung cancer is to be resected and/or radiation therapy is to be administered.

14. The use 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 use of any one of the preceding claims, wherein treating cancer in the lung does not result in annamycin-induced toxicity of the lung that would contraindicate repeated administration of the annamycin.

16. The use of any one of the preceding claims, wherein treating cancer in the lung does not result in annamycin-induced systemic toxicity that would contraindicate repeated administration of the annamycin.

17. The use of any one of the preceding claims, wherein the therapeutically effective amount of liposomal annamycin is to be administered weekly.

18. The use of any one of claims 1 to 16, wherein the therapeutically effective amount of liposomal annamycin is to be administered every two, three, or four weeks.

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

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

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