strategies in the management of hormone refractory prostate cancer. *Cancer Treat Rev.* 2003; 29:171-187.) Docetaxel is administered via a one-hour infusion every three weeks over ten or more cycles.

[0014] Docetaxel, when used with or without prednisone, was the first chemotherapy drug proven to help patients with advanced prostate cancer live longer. (Tannock IF, de Wit R, Berry WR, et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. *N. Engl. J. Med.* 351 (15): 1502–12 (2004)). Treatments with docetaxel in combination with estramustine or prednisone have made it possible to treat cancers that are resistant to hormone deprivation. The TAX 327 trial was a phase III study that showed significant survival benefit from docetaxel in androgen-independent metastatic prostate cancer. Compared with mitoxantrone treatment, docetaxel treated patients showed a 12% overall response rate and mitoxantrone showed a 7% overall response rate. Another large advantage of docetaxel was increased quality of life. (Berthold DR, Pond GR, Soban F, De Wit R, Eisenberger M, Tannock IF. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer: Updated survival in the TAX 327 study. *J Clin Oncol.* 2008; 26(2):242-245.)

[0015] Docetaxel is a chemotherapeutic agent and is a cytotoxic compound and so is effectively a biologically damaging drug. As with all chemotherapy, adverse effects are common and many varying side-effects have been documented. There is a need for enhanced cancer therapy regimens that increase effectiveness of the therapy while reducing side effects and toxicity resulting from the chemotherapeutic treatment.

[0016] Compositions of botanicals comprising therapeutically effective amounts of two or more of an extract of *Ganoderma lucidum*, an extract of *Salvia miltiorrhiza* and an extract of *Scutellaria barbata* for prevention and therapy of cancer have been reported by Dao et al. (US Pat.. No. 8,173,177).

SUMMARY OF THE INVENTION

[0017] The present ~~invention~~ disclosure relates to combinations of docetaxel and compositions botanical extracts for treatment and therapy of prostate cancer.

[0017a] In one aspect of the disclosure, there is provided the use of an effective amount of a botanical composition in the manufacture of a medicament for the treatment or reduction of the severity of prostate cancer in a subject, or reducing a symptom associated with prostate

cancer, wherein the botanical composition comprises: two or more extracts in an organic medium of *Ganoderma lucidum*, *Salvia miltiorrhiza* and *Scutellaria barbata*, wherein each extract comprises from about 10 to about 50 percent w/w of *Ganoderma lucidum* and *Scutellaria barbata* and about 1 to about 10 percent w/w of *Salvia miltiorrhiza*; wherein the medicament is to be co-administered with an effective amount of docetaxel, and wherein the co-administration of docetaxel and the botanical composition achieves more effective therapy than administration of either agent alone.

[0018] The compositions of botanical extracts can be used to reduce or alleviate the side affects when used with standard non-botanical chemotherapies. Side effects are reduced by inhibiting inflammatory responses, modulating immune responses, reducing oxidative stress,

modulating immune responses, inhibiting viral and microbial infections, modulating cell proliferative responses or other biological responses. The compositions ~~of the invention~~disclosed herein may also alleviate side affects of standard therapeutic agents by balancing general biological responses against perturbations in specific biological pathways due to treatment with the therapeutic agent.

[0019] In a preferred embodiment, the composition comprises combinations of two or more extracts of *Ganoderma lucidum*, *Scutellaria barbata*, *Scutellaria baicalensis*, *Salvia miltiorrhiza*, and optionally, *Hippophae rhamnoides* (sea buckthorn).

[0020] In one embodiment, this method comprises treatment or therapy of prostate cancer in a human is provided, the method comprising: administering an effective amount of a botanical composition that is effective for reducing androgen receptor protein expression; and administering concurrently an effective amount of a compound having anti-androgen activity, wherein the concurrent administration of the compound and the botanical composition achieves more effective therapy than either agent alone. Botanical compositions comprising non-alcoholic organic extracts of *Ganoderma lucidum*, *Salvia miltiorrhiza* and *Scutellaria barbata* in conjunction with docetaxel therapy are used.

[0021] Methods are disclosed for treatment or reducing the severity of prostate cancer in a subject, the method comprising: administering an effective amount of a botanical composition comprising two or more extracts in an organic medium of *Ganoderma lucidum*, *Salvia miltiorrhiza* and *Scutellaria barbata*, wherein each extract comprises from about 10 to about 50 percent w/w of *Ganoderma lucidum* and *Scutellaria barbata* and about 1 to about 10 percent w/w of *Salvia miltiorrhiza*, and wherein the botanical composition is effective for reducing a symptom associated with prostate cancer; and co-administering an effective amount of docetaxel, wherein the co-administration of the compound and the botanical composition achieves more effective therapy than administration of either agent alone.

[0022] In some ~~aspects~~embodiments, the prostate cancer symptom is a size of a prostate tumor. In some aspects, the prostate tumor is an androgen-dependent adenocarcinoma. In some aspects, the prostate cancer symptom is a growth rate of prostate cancer tissue. In some aspects, the prostate cancer tissue is from an androgen-dependent adenocarcinoma. In some embodiments, the prostate cancer symptom is a level of prostate specific antigen (PSA).

CLAIMS

~~What is claimed is:~~

1. ~~A method for treatment or reducing the severity of prostate cancer in a subject, the method comprising:~~

~~administering~~ Use of an effective amount of a botanical composition in the manufacture of a medicament for the treatment or reduction of the severity of prostate cancer in a subject, or reducing a symptom associated with prostate cancer, wherein the botanical composition comprises: ~~comprising~~ two or more extracts in an organic medium of *Ganoderma lucidum*, *Salvia miltiorrhiza* and *Scutellaria barbata*, wherein each extract comprises from about 10 to about 50 percent w/w of *Ganoderma lucidum* and *Scutellaria barbata* and about 1 to about 10 percent w/w of *Salvia miltiorrhiza*, ~~and wherein the botanical composition is effective for reducing a symptom associated with prostate cancer; and~~

~~co-administering~~ wherein the medicament is to be co-administered with an effective amount of docetaxel, and

wherein the co-administration of docetaxel~~the compound~~ and the botanical composition achieves more effective therapy than administration of either agent alone.

2. The ~~method~~ use of claim 1, wherein the prostate cancer symptom is a size of a prostate tumor.

3. The ~~method~~ use of claim 2, wherein the prostate tumor is an androgen-dependent adenocarcinoma.

4. The ~~method~~ use of claim 1, wherein the prostate cancer symptom is a growth rate of prostate cancer tissue.

5. The ~~method~~ use of claim 4, wherein the prostate cancer tissue is from an androgen-dependent adenocarcinoma.

6. The ~~method~~ use of claim 1, wherein the prostate cancer symptom is a level of prostate specific antigen (PSA).

7. The ~~method~~ use of claim 1, wherein the co-adminstration comprises daily administration of the botanical composition and periodic administration of docetaxel over a time period.

8. The ~~method~~ use of claim 6, wherein the time period is 3 weeks.

9. The ~~method~~ use of claim 1, wherein the extract is a non-alcoholic organic extract.

10. The ~~method~~ use of claim 8, wherein the extract is made with ethyl acetate ester.

11. The ~~method~~ use of claim 1, wherein co-administration of docetaxel and the botanical composition results in reduced toxicity and side-effects compared to administration of an equivalent dosage of docetaxel alone.

12. The ~~method~~ use of claim 1, wherein the botanical composition comprises 2% w/w of *Salvia miltiorrhizza* extract.

13. The ~~method~~ use of claim 1, wherein the botanical composition comprises one or more of an emulsifier, a surfactant, an antioxidant and a diluent.

14. The ~~method~~ use of claim 13, wherein the emulsifier is selected from one or more of fatty acids, polyoxyethylene glycerol esters of fatty acids, polooxylated castor oil, ethylene glycol esters, propylene glycol esters glyceryl esters of fatty acids, sorbitan esters, polyglyceryl esters, fatty alcohol ethoxylates, ethoxylated propoxylated block copolymers, polyethylene glycol esters of fatty acids, cremophores, glycerol monocaprylate/caprate, Cremophor EL, oleic acid, Labrasol, Gelucire, Capryol, Captex, Acconon, transcutol, and triacetin.

15. The ~~method~~ use of claim 13, wherein the antioxidant is selected from ascorbic acid and alpha tocopherol.

16. The ~~method~~ use of claim 13, wherein the diluent is soya oil.

17. The ~~method~~ use of claim 1, wherein docetaxel is to be administered intra-venously.

18. The ~~method~~ use of claim 1, wherein the botanical composition is to be administered orally.

19. The ~~method~~ use of claim 1, wherein the prostate cancer is a castration-resistant prostate cancer.

20. The ~~method~~ use of claim 1, wherein the prostate cancer is an androgen-sensitive prostate cancer.

21. The ~~method~~ use of claim 1, wherein the docetaxel is to be administered in a sub-therapeutic dose.

22. The ~~method~~ use of claim 1, wherein botanical composition comprises an effective amount of Ganoderma lucidum extract selected from 10%, 15%, 20%, 30%, 33%, 35%, 40%, 42%, 44%, 45%, 46%, 46.5%, 47%, 47.5%, 48%, 48.5%, 49%, 49.5% and 50%.

23. The ~~method~~ use of claim 1, wherein botanical composition comprises an effective amount of Scutellaria barbata extract selected from 10%, 15%, 20%, 30%, 33%, 35%, 40%, 42%, 44%, 45%, 46%, 46.5%, 47%, 47.5%, 48%, 48.5%, 49%, 49.5% and 50%.

24. The ~~method~~ use of claim 1, wherein botanical composition comprises an effective amount of Salvia miltiorrhiza extract selected from 1%, 1.5%, 2%, 2.5%, 3%, 3.5%, 4%, 4.5%, 5%, 5.5%, 6%, 6.5%, 7%, 7.5%, 8%, 8.5%, 9%, 9.5% and 10%.

25. The ~~method~~ use of claim 1, wherein botanical composition is in a dosage form suitable for oral administration.