hemorrhage. Increases in white blood cells, neutrophils and lymphocytes, lead to a decrease in infectious complications.

[0013a] In one aspect, the invention relates to the use of a pharmaceutical composition in the manufacture of a medicament for mitigating adjustment of a predetermined chemotherapy and/or chemoradiotherapy regimen in a subject with cancer, wherein the composition comprises a therapeutically effective amount of IL-12, and wherein the pharmaceutical composition is to be administered in a therapeutically effective amount to a subject receiving a predetermined chemotherapy and/or chemoradiotherapy regimen, wherein: (a) the predetermined chemotherapy and/or chemoradiotherapy regimen comprises cycles of the chemotherapy and/or chemoradiotherapy, and (b) the administration of IL-12 reduces the likelihood and/or severity of occurrence of at least two cytopenias inducible by chemotherapy and/or chemoradiotherapy, wherein the need for subsequent adjustment of the chemotherapy and/or chemoradiotherapy dose regimen resulting from the induction of cytopenia is mitigated.

[0013b] In another aspect, there is provided the use of a pharmaceutical composition comprising IL-12 in the manufacture of a medicament for the treatment of at least one chemotherapy-induced cytopenia in a subject with cancer following exposure of the subject to chemotherapeutic agents, wherein administration of a therapeutically effective amount of the pharmaceutical composition results in diminishment of at least one chemotherapy-induced cytopenia.

[0014] The inventions described and claimed herein have many attributes and embodiments including, but not limited to, those set forth or described or referenced in this Brief Summary. It is not intended to be all-inclusive and the inventions described and claimed herein are not limited to or by the features or embodiments identified in this Brief Summary, which is included for purposes of illustration only and not restriction. Additional embodiments may be disclosed in the Detailed Description below.

BRIEF DESCRIPTION OF THE FIGURES

[0015] Figure 1 A-B: Blood Recovery Profiles for Vehicle and rMuIL-12 Administered Before and After Myelosuppresive Radiation (625 rad). Blood cell recovery profiles are shown for the EL4 lymphoma tumor model (a) and the Lewis lung cancer model (b) for neutrophils, red blood cells and platelets. Pre-radiation blood values reflect an average of all animals in both groups before radiation and tumor inoculation. The normal threshold value for murine blood cell counts is indicated by the dashed line. During days 14-21 in both tumor models, rMuIL-12—treated mice showed statistically significant improvements in blood cell counts as

WHAT IS CLAIMED IS:

1. Use of a pharmaceutical composition in the manufacture of a medicament for mitigating adjustment of a predetermined chemotherapy and/or chemoradiotherapy regimen in a subject with cancer, wherein the composition comprises a therapeutically effective amount of IL-12, and wherein:

the pharmaceutical composition is to be administered in a therapeutically effective amount to a subject receiving a predetermined chemotherapy and/or chemoradiotherapy regimen, wherein:

(a) the predetermined chemotherapy and/or chemoradiotherapy regimen comprises cycles of the chemotherapy and/or chemoradiotherapy, and

(b) the administration of IL-12 reduces the likelihood and/or severity of occurrence of at least two cytopenias inducible by chemotherapy and/or chemoradiotherapy, wherein the need for subsequent adjustment of the chemotherapy and/or chemoradiotherapy dose regimen resulting from the induction of cytopenia is mitigated.

2. The use of claim 1, wherein the chemotherapy and/or chemoradiotherapy dose regimen adjustment comprises modification of dose amount and frequency of administration, including dose fraction/ dose titration and/or dose reduction.

3. The use of claim 1 or 2, wherein the administration of IL-12 induces anti-tumor responses.

4. The use of any one of claims 1-3, wherein the combined modality of the IL-12 administration with chemotherapy and/or chemoradiotherapy results in an increase in the survival of the subject.

5. The use of claim 4, wherein the survival is progression-free survival.

6. The use of claim 4, wherein the survival is the overall survival of the subject.

7. The use of any one of claims 1-6, wherein one of the at least two cytopenias is lymphopenia.

8. The use of any one of claims 1-7, wherein the cytopenias are selected from at least two of neutropenia, leucopenia, anemia, thrombocytopenia, and lymphopenia.

9. The use of any one of claims 1-8, wherein one of the at least two cytopenias is neutropenia.

10. The use of claim 7 or 8, wherein the lymphopenia comprises low levels of at least one of lymphocyte subsets comprising CD4+, CD8+, CD8+memory cells, and NK cells.

11. Use of a pharmaceutical composition comprising IL-12 in the manufacture of a medicament for the treatment of at least one chemotherapy-induced cytopenia in a subject with cancer following exposure of the subject to chemotherapeutic agents, wherein administration of a therapeutically effective amount of the pharmaceutical composition results in diminishment of at least one chemotherapy-induced cytopenia.

12. The use of claim 11, wherein the chemotherapeutic agent is to be administered to the subject as a combined modality in combination with exposure to a dose of radiation.

13. The use of claim 11 or 12, wherein the pharmaceutically effective dose of IL-12 is less than about 300 ng/kg.

14. The use of claim 11 or 12, wherein the pharmaceutically effective dose of IL-12 is two or more doses of less than about 300 ng/kg for each dose.

15. The use of claim 11 or 12, wherein the one or more pharmaceutically effective dose(s) of IL-12 is less than about 200 ng/kg.

16. The use of claim 11 or 12, wherein the one or more pharmaceutically effective dose(s) of IL-12 is less than about 100 ng/kg.

17. The use of any one of claims 11-16, wherein the one or more pharmaceutically effective dose(s) of IL- I 2 are given before chemotherapeutic agent exposure.

18. The use of any one of claims 11-16, wherein the one or more pharmaceutically effective dose(s) of IL-12 are given before and after chemotherapeutic agent exposure.

19. The use of any one of claims 11-16, wherein the one or more pharmaceutically effective dose(s) of IL-12 are given after chemotherapeutic agent exposure.

20. The use of any one of claims 11-19, wherein the IL-12 is a rHuIL-12.

21. The use of any one of claims 11-20, wherein the chemotherapeutic agent is a platinum-based chemotherapy.

22. The use of any one of claims 1-10, wherein one of the at least two cytopenias is thrombocytopenia.

23. The use of any one of claims 11-21, wherein the at least one chemotherapy-induced cytopenia comprises thrombocytopenia.