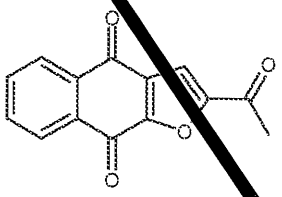
WHAT IS CLAIMED IS:

1. A method of treating a cancer in a human subject, the method comprising administering to a subject in need thereof a therapeutically effective amount of a compound having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof, wherein the compound is administered to the subject at a total daily dose in a range from about 80 mg to about 2000 mg.

2. The method of claim 1, wherein the compound is administered to the subject at a total daily dose of about 960 mg.

3. The method of claim 1 or claim 2, wherein the compound is administered to the subject in two daily doses.

4. The method of claim 3, wherein each dose is about 480 mg.

5. The method of claim 1, wherein the compound is administered to the subject as a tablet or capsule.

6. The method of claim 5, wherein the tablet or capsule comprises a dose of about 80 mg.

7. The method of any one of claims 1 to 6, wherein the interval between administrations of the compound is in the range from about 4 hours to about 16 hours.

8. The method of claim 7, wherein the compound is administered to the subject at a dose selected from the group consisting of about 80 mg BID, about 160 mg BID, about 320

mg BID, about 400 mg BID, about 480 mg BID, about 500 mg BID, and about 600 mg BID.

9. The method of any one of claims 1 to 6, wherein the interval between administrations of the compound is selected from the group consisting of at least about 4 hours, at least about 5 hours, at least about 6 hours, at least about 7 hours, at least about 8 hours, at least about 9 hours, at least about 10 hours, at least about 11 hours, at least about 12 hours, at least about 13 hours, at least about 14 hours, at least about 15 hours and at least about 16 hours.

10. The method of any one of claims 1 to 6, wherein the interval between administrations is about 12 hours.

11. The method of claim 1, wherein each dose is about 480 mg BID and the interval between administrations is about 12 hours.

12. The method of claim 1, wherein each dose is about 80 mg BID and the interval between administrations is about 12 hours.

13. The method of claim 1, wherein each dose is about 400 mg BID and the interval between administrations is about 12 hours.

14. The method of claim 1, wherein each dose is about 300 mg BID and the interval between administrations is about 12 hours.

15. The method of claim 1, wherein the compound is administered orally in conjunction with a fluid on an empty stomach.

16. The method of claim 15, wherein the fluid comprises a milk or water.

17. The method of claim 1, wherein the compound is a polymorph selected from

(a) a polymorph characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 2 of Patent Publications WO 2011/116398 and WO 2011/116399;

(b) a polymorph of 2-acetyl-4H, 9H-naphtho[2,3-b]furan-4,9-dione characterized by an X-ray diffraction pattern including one or more peaks from the group consisting of peaks at least at about 10.2, 11.9, 14.1, 14.5, 17.3, 22.2, and 28.1 degrees 2θ;

(c) a polymorph of 2-acetyl-4H, 9H-naphtho[2,3-b]furan-4,9-dione characterized by an X-ray diffraction pattern including two or more peaks from a peak at least at about 10.2 degrees 2θ, a peak at least at about 11.9 degrees 2θ, a peak at least at about 14.1 degrees 2θ, a peak at least at about 14.5 degrees 2θ, a peak at least at about 17.3 degrees 2θ, a peak at least at about 22.2 degrees 2θ, and a peak at least at about 28.1 degrees 2θ and any combinations thereof;

(d) a polymorph characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 3 of Patent Publications WO 2011/116398 and WO 2011/116399;

(e) a polymorph of 2-acetyl-4H, 9H-naphtho[2,3-b]furan-4,9-dione characterized by an X-ray diffraction pattern including one or more peaks selected from the group consisting of peaks at least at about 7.5, 9.9, 12.3, 15, 23, 23.3, 24.6, and 28.4 degrees 2θ; and

(f) a polymorph of 2-acetyl-4H, 9H-naphtho[2,3-b]furan-4,9-dione characterized by an X-ray diffraction pattern including two or more peaks from a peak at least at about 7.5 degrees 2θ, a peak at least at about 9.9 degrees 2θ, a peak at least at about 12.3 degrees 2θ, a peak at least at about 15 degrees 2θ, a peak at least at about 23 degrees 2θ, a peak at least at about 23.3 degrees 2θ, a peak at least at about 24.6 degrees 2θ, and a peak at least at about 28.4 degrees 2θ and any combinations thereof.

18. The method of any one of the preceding claims, wherein the compound is in a particle form, and wherein the particle has a diameter of or equal to or less than about 20 micrometers.

19. The method of claim 1, wherein the compound is in a pharmaceutical composition comprising a population of particles of the compound, and wherein a fraction of the cumulative total of the particles have a diameter in the range of 0.2 μm to 20 μm.

20. The method of claim 1, wherein the compound is in a pharmaceutical composition comprising a population of particles of the compound, and wherein 50% of the cumulative total of the particles (D50) have a diameter in the range from about 0.5 to about 5 μm.

21. The method of claim 1, wherein the compound is in a pharmaceutical composition comprising a population of particles of the compound, and wherein 50% of the cumulative total of the particles (D50) have a diameter of about 2 μm.

22. The method of any one of the preceding claims, wherein the compound is administered in a formulation with the API having a purity greater than or equal to 95.0% as determined by high performance liquid chromatography (HPLC), nuclear magnetic resonance (NMR) or both HPLC and NMR, and wherein the composition comprises less than or equal to 5% impurities.

23. The method of claim 1, wherein the cancer is selected from the group consisting of gastric and gastroesophageal adenocarcinoma, colorectal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma21. The method of claim 1, wherein the cancer is gastric cancer

24. The method of claim 1, wherein the cancer is gastric/gastroesophageal junction adenocarcinoma.

25. The method of claim 1, wherein the cancer is refractory.

26. The method of claim 1, wherein the cancer is recurrent.

27. The method of claim 1, wherein the cancer is metastatic.

28. The method of claim 1, wherein the cancer is associated with overexpression of STAT3.

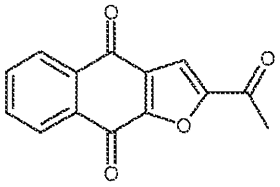
29. The method of claim 1, the method further comprising detecting a level of phosphorylated STAT3 (p-STAT3) in a patient tissue, where the level of p-STAT3 is used as a biomarker for patient selection.

30. The method of claim 1, wherein the cancer is associated with nuclear β-catenin overexpression.

31. The method of claim 1, the method further comprising detecting nuclear β-catenin expression in a patient's tissue, where such nuclear β-catenin expression is used as a biomarker for patient selection.

32. A method of curative or prophylactic cancer treatment, the method comprising the steps of:

(a) administering to a subject in need of a curative or prophylactic cancer treatment a dosage of a first agent having the structure

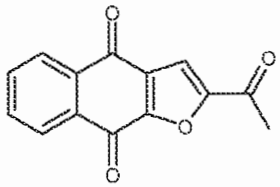


or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof; and

(b) administering to the subject a dosage of an antimitotic agent or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof.

33. A method of curative or prophylactic cancer treatment in administering to a subject to the paclitaxel (Abraxane / Taxol), the method comprising the steps of:

(a) administering to a subject in need of a curative or prophylactic cancer treatment a dosage of a first agent having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof;
wherein the dosage of the first agent is administered before or after administering the paclitaxel (Abraxane / Taxol) to the subject.

34. The method of claim 32, wherein the antimitotic agent is selected from the group consisting of paclitaxel (Abraxane/Taxol), docetaxel (taxotere), BMS-275183, xyotax, tocosal, vinorlebine, vincristine, vinblastine, vindesine, vinzolidine, etoposide (VP-16), teniposide (VM-26), ixabepilone, larotaxel, ortataxel, tesetaxel, and ispinesib.

35. The method of claim 33, wherein the antimitotic agent comprises paclitaxel (Abraxane/Taxol).

36. The method of claim 32 or 33, wherein the cancer is selected from the group consisting of gastric cancer gastroesophageal junction cancer, and esophageal cancer.

37. The method of claim 32 or 33, wherein the cancer is gastric/gastroesophageal adenocarcinoma.

38. The method of claim 32 or 33, wherein the cancer is refractory.

39. The method of claim 32 or 33, wherein the cancer is recurrent.

40. The method of claim 32 or 33, wherein the cancer is metastatic.

41. The method of claim 32 or 33, the method further comprising detecting a level of phosphorylated STAT3 (p-STAT3) in a patient tissue, where the level of p-STAT3 is used as a biomarker for patient selection.

42. The method of claim 32 or 33, wherein the cancer is associated with overexpression of nuclear β-catenin.

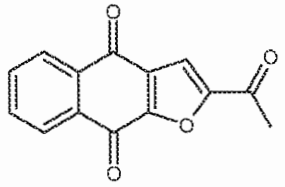
43. The method of claim 32 or 33, the method further comprising detecting a nuclear β-catenin expression in a patient's tissue, where nuclear β-catenin expression is used as a biomarker for patient selection.

44. A method of treating cancer in a selected patient population, the method comprising the steps of:

(a) measuring a level of phosphorylated STAT3 (p-STAT3) in a biological sample obtained from a patient candidate diagnosed of a cancer;

(b) confirming that the patient candidate's p-STAT3 level is above a benchmark level; and

(c) administering to the patient candidate a therapeutically effective amount of a compound having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof.

45. The method of claim 44, wherein the cancer is selected from the group consisting of esophageal cancer, gastroesophageal junction cancer, gastroesophageal adenocarcinoma, chondrosarcoma, colorectal cancer, colon adenocarcinoma, rectal adenocarcinoma, colorectal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma, gastric adenocarcinoma, and adrenocorticoid carcinoma.

46. The method of claim 44, wherein the cancer is colorectal adenocarcinoma.

47. The method of claim 44, wherein the cancer is refractory.

48. The method of claim 44, wherein the cancer is recurrent.

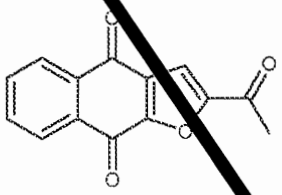
49. The method of claim 44, wherein the cancer is metastatic.

50. A method of treating cancer in a selected patient population, the method comprising the steps of:

(d) detecting nuclear β-catenin expression in a biological sample obtained from a patient candidate diagnosed of a cancer;

(e) confirming that significant β-catenin expression is detected in cell nucleus in the sample from the patient candidate; and

(f) administering to the patient candidate a therapeutically effective amount of a compound having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof.

51. The method of claim 50, wherein the cancer is selected from the group consisting of gastric and gastroesophageal adenocarcinoma, esophageal adenocarcinoma, colorectal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma, and adrenocorticoid carcinoma.

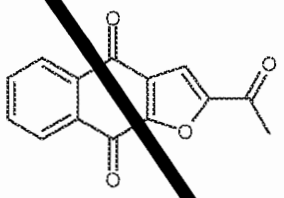
52. The method of claim 50, wherein the cancer is colorectal adenocarcinoma.

53. The method of claim 50, wherein the cancer is refractory.

54. The method of claim 50, wherein the cancer is recurrent.

55. The method of claim 50, wherein the cancer is metastatic.

56. A method of treating cancer in a human subject, the method comprising administering to a subject diagnosed of a cancer a therapeutically effective amount of a compound having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof, wherein the cancer is colorectal cancer, colon adenocarcinoma or rectal adenocarcinoma.

57. The method of claim 56, wherein the compound is administered to the subject in two daily doses totaling in a range from about 80 mg to about 2000 mg.

58. The method of claim 56, wherein the compound is administered to the subject in doses of about 480 mg.

59. The method of claim 56, wherein the interval between administrations of the compound is in the range from about 4 hours to about 16 hours.

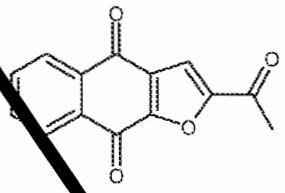
60. The method of claim 56, wherein the compound is administered to the subject at a dose selected from the group consisting of about 80 mg BID, about 160 mg BID, about 320 mg BID, about 400 mg BID, about 480 mg BID, and about 500 mg BID.

61. The method of claim 56, wherein the cancer is refractory.

62. The method of claim 56, wherein the cancer is recurrent.

63. The method of claim 56, wherein the cancer is metastatic.

64. A pharmaceutical composition, comprising:
a therapeutically effective amount of an active ingredient having the structure



;

a surfactant comprising sodium lauryl sulfate (SLS) or sodium dodecyl sulfate (SDS);
Gelucire (lauroyl polyoxylglycerides); and
Labrafil (linoleoyl polyoxylglycerides).

65. The pharmaceutical composition of claim 64, further consisting of, by weight, about 27.18% in the active ingredient, about 0.27% in the surfactant, about 14.51% in Gelucire, and about 58.04% in Labrafil.

66. The pharmaceutical composition of claim 64, further consisting of about 125 mg of the active ingredient, about 1.2 mg of the surfactant, about 66.8 mg of Gelucire, and about 267 mg of Labrafil.

67. The pharmaceutical composition of claim 64, further consisting of about 80 mg of the active ingredient, about 0.8 mg of the surfactant, about 42.7 mg of Gelucire, and about 170.9 mg of Labrafil.

68. An item of manufacture comprising the pharmaceutical composition of any of claims 64-67 housed in a capsule.

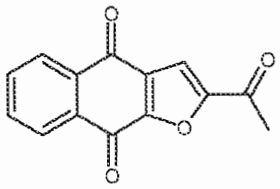
69. The item of manufacture of claim 68, wherein the capsule is of size 1 or smaller.

70. A method of treating cancer in a selected patient population, the method comprising the steps of:

(a) measuring a level and/or subcellular localization of one or more cancer stemness markers selected from phosphorylated STAT3 (p-STAT3), β-catenin, and NANOG in a biological sample obtained from a patient candidate diagnosed of a cancer;

(b) confirming that the patient candidate's cancer stemness marker level and/or subcellular localization is above a benchmark level; and

(c) administering to the patient candidate a therapeutically effective amount of a compound having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof.

71. The method of claim 70, wherein the cancer is selected from the group consisting of colorectal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma, gastric/gastroesophageal adenocarcinoma, esophageal adenocarcinoma, and adrenocorticoid carcinoma.

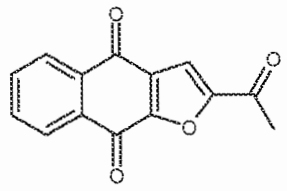
72. The method of claim 70, wherein the cancer is colorectal adenocarcinoma.

73. The method of claim 70, wherein the cancer is refractory.

74. The method of claim 70, wherein the cancer is recurrent.

75. The method of claim 70, wherein the cancer is metastatic.

76. A method of treating a cancer in a human subject, the method comprising administering to a subject in need thereof a therapeutically effective amount of a compound having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof, and administering a therapeutically effective amount of paclitaxel.

77. The method of claim 76, wherein the compound is administered to the subject at a total daily dose in a range from about 80 mg to about 2000 mg.

78. The method of claim 76, wherein the compound is administered to the subject at a total daily dose of about 960 mg.

79. The method of any one of claims 76 to 78, wherein the compound is administered to the subject in two daily doses.

80. The method of claim 79, wherein each dose is about 480 mg.

81. The method of any one of claims 76 to 80, wherein the interval between administrations of the compound is in the range from about 4 hours to about 16 hours.

82. The method of claim 81, wherein the compound is administered to the subject at a dose selected from the group consisting of about 80 mg BID, about 160 mg BID, about 320 mg BID, about 400 mg BID, about 480 mg BID, and about 500 mg BID.

83. The method of any one of claims 76 to 80, wherein the interval between administrations of the compound is selected from the group consisting of at least 4 hours, at least 5 hours, at least 6 hours, at least 7 hours, at least 8 hours, at least 9 hours, at least 10 hours, at least 11 hours, at least 12 hours, at least 13 hours, at least 14 hours, at least 15 hours and at least 16 hours.

84. The method of any one of claims 76 to 80, wherein the interval between administrations is about 12 hours.

85. The method of claim 76, wherein each dose is about 480 mg BID and the interval between administrations is about 12 hours.

86. The method of claim 76, wherein each dose is about 80 mg BID and the interval between administrations is about 12 hours.

87. The method of claim 76, wherein each dose is about 400 mg BID and the interval between administrations is about 12 hours.

88. The method of claim 76, wherein each dose is about 320 mg BID and the interval between administrations is about 12 hours.

89. The method of claim 76, wherein the compound is administered orally in conjunction with a fluid on an empty stomach.

90. The method of claim 76, wherein the fluid comprises a milk or water.

91. The method of claim 76, wherein the paclitaxel is administered to the subject at a total weekly dose in a range from about 40 mg/m^2 to about 100 mg/m^2.

92. The method of claim 76, wherein the paclitaxel is administered to the subject at a total weekly dose of about 80 mg/m^2.

93. The method of claim 76, wherein the paclitaxel is administered to the subject through IV.

94. The method of claim 76, wherein the compound is a polymorph selected from:

(a) a polymorph characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 2 of Patent Publications WO 2011/116398 and WO 2011/116399;

(b) a polymorph of 2-acetyl-4H, 9H-naphtho[2,3-b]furan-4,9-dione characterized by an X-ray diffraction pattern including one or more peaks from the group consisting of peaks at least at about 10.2, 11.9, 14.1, 14.5, 17.3, 22.2, and 28.1 degrees 2θ;

(c) a polymorph of 2-acetyl-4H, 9H-naphtho[2,3-b]furan-4,9-dione characterized by an X-ray diffraction pattern including two or more peaks from a peak at least at about 10.2 degrees 2θ, a peak at least at about 11.9 degrees 2θ, a peak at least at about 14.1 degrees 2θ, a peak at least at about 14.5 degrees 2θ, a peak at least at about 17.3 degrees 2θ, a peak at least at

about 22.2 degrees 2θ, and a peak at least at about 28.1 degrees 2θ and any combinations thereof;

(d) a polymorph characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 3 of Patent Publications WO 2011/116398 and WO 2011/116399;

(e) a polymorph of 2-acetyl-4H, 9H-naphtho[2,3-b]furan-4,9-dione characterized by an X-ray diffraction pattern including one or more peaks selected from the group consisting of peaks at least at about 7.5, 9.9, 12.3, 15, 23, 23.3, 24.6, and 28.4 degrees 2θ; and

(f) a polymorph of 2-acetyl-4H, 9H-naphtho[2,3-b]furan-4,9-dione characterized by an X-ray diffraction pattern including two or more peaks from a peak at least at about 7.5 degrees 2θ, a peak at least at about 9.9 degrees 2θ, a peak at least at about 12.3 degrees 2θ, a peak at least at about 15 degrees 2θ, a peak at least at about 23 degrees 2θ, a peak at least at about 23.3 degrees 2θ, a peak at least at about 24.6 degrees 2θ, and a peak at least at about 28.4 degrees 2θ and any combinations thereof.

95. The method of any one of the preceding claims, wherein the compound is in a particle form, and wherein the particle has a diameter of or equal to or less than about 20 micrometers.

96. The method of claim 76, wherein the compound is in a pharmaceutical composition comprising a population of particles of the compound, and wherein a fraction of the cumulative total of the particles have a diameter of about 0.5 μm to about 5 μm.

97. The method of claim 76, wherein the compound is in a pharmaceutical composition comprising a population of particles of the compound, and wherein 50% of the cumulative total of the particles (D50) have a diameter of about 2 μm.

98. The method of any one of the preceding claims, wherein the compound is administered in a formulation with API having a purity greater than or equal to 95.0% as determined by high performance liquid chromatography (HPLC), nuclear magnetic

resonance (NMR) or both HPLC and NMR, and wherein the composition comprises less than or equal to 5% impurities.

99. The method of any one of the preceding claims, wherein the cancer is selected from the group consisting of gastric and gastroesophageal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma, and esophageal adenocarcinoma.

100. The method of claim 76, wherein the cancer is gastric and gastroesophageal adenocarcinoma.

101. The method of claim 76, wherein the cancer is selected from the group consisting of colorectal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma, gastric adenocarcinoma, and adrenocorticoid carcinoma.

102. The method of claim 76, wherein the cancer is refractory.

103. The method of claim 76, wherein the cancer is recurrent.

104. The method of claim 76, wherein the cancer is metastatic.

105. The method of claim 76, wherein the cancer is associated with overexpression of STAT3.

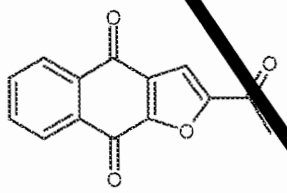
106. The method of claim 76, the method further comprising detecting a level of phosphorylated STAT3 (p-STAT3) in a patient tissue, where the level of p-STAT3 is used as a biomarker for patient selection.

107. The method of claim 76, wherein the cancer is associated with nuclear β-catenin expression.

108. The method of claim 76, the method further comprising detecting β-catenin expression in a patient's tissue, where such β-catenin expression is used as a biomarker for patient selection.

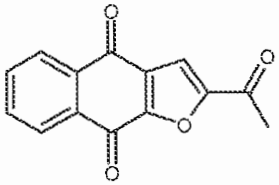
109. The method of claim 76, wherein significant β-catenin expression is detected in cell nucleus.

110. A method of treating cancer in a patient whose β-catenin expression in cell is detected in cell nucleus, comprising administering to the patient a therapeutically effective amount of a compound having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof.

111. A method of treating cancer in a patient whose β-catenin expression in cell is detected in cell nucleus as opposed to in cell membrane, comprising administering to the patient a therapeutically effective amount of a compound having the structure

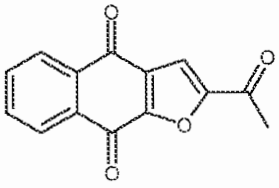


or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof.

112. The method according to claim 111, wherein the β-catenin is at a level of medium to strong expression of β-catenin such that β-catenin is detected in 20% or more tumor cells.

113. A pharmaceutical composition, comprising:

(a) a therapeutically effective amount of an active ingredient having the structure



(b) polyoxylglycerides of which HLB is more than 10; and

(c) polyoxylglycerides of which HLB is less than 10.

114. A pharmaceutical composition, according to claim 113, wherein the composition further comprises a surfactant.

115. A pharmaceutical composition, according to claim 113, wherein the polyoxylglycerides of which HLB is more than 10, is selected from the group consisting of lauroyl polyoxylglycerides and stearoyl polyoxylglycerides.

116. A pharmaceutical composition, according to claim 113, wherein the polyoxylglycerides of which HLB is less than 10 is linoleoyl polyoxylglycerides.

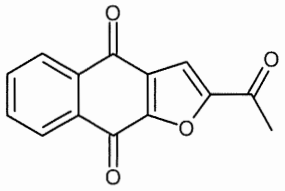
117. A pharmaceutical composition, according to claim 114, wherein the surfactant is sodium lauryl sulfate (SLS) or sodium dodecyl sulfate.

118. A pharmaceutical composition, according to claim 113 or claim 114, wherein the polyoxylglycerides of which HLB is more than 10, is selected from the group consisting of lauroyl polyoxylglycerides and stearoyl polyoxylglycerides, and the polyoxylglycerides of which HLB is less than 10 is linoleoyl polyoxylglycerides.

119. A pharmaceutical composition, according to claim 114, wherein the polyoxylglycerides of which HLB is more than 10, is selected from the group consisting of lauroyl polyoxylglycerides and stearoyl polyoxylglycerides, the polyoxylglycerides of which HLB is less than 10 is linoleoyl polyoxylglycerides, and the surfactant is sodium lauryl sulfate (SLS) or sodium dodecyl sulfate.

Claims

1. A compound having the structure

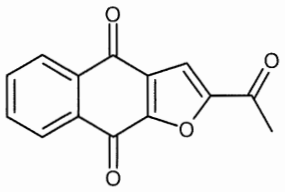


or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof, for use in the treatment of cancer, wherein in use the compound is to be administered to a subject in need thereof a therapeutically effect amount of the compound and a therapeutically effective amount of paclitaxel.

2. The compound according to claim 1, wherein the compound is to be administered to the subject at a total daily dose:

a) in a range from about 80 mg to about 2000 mg; or
b) of about 960 mg;

3. A compound having the structure

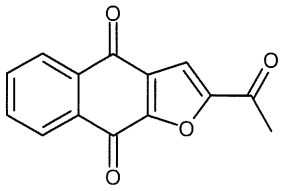


or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof, for use in the treatment of cancer wherein the compound is to be administered to the subject at a total daily dose:

a) in a range from about 80 mg to about 2000 mg; or
b) of about 960 mg;

or wherein the compound is to be administered to a subject in need thereof a therapeutically effect amount of the compound and a therapeutically effective amount of paclitaxel.

4. A compound having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof, for use in the treatment of cancer in a selected patient population, wherein the use comprises the steps of:
(a) measuring a level and/or subcellular localization of one or more cancer sternness markers selected from phosphorylated STATS (p- STAT3), β-catenin, and NANOG in a biological sample obtained from a patient candidate diagnosed of a cancer;
(b) confirming that the patient candidate's cancer sternness marker level and/or subcellular localization is above a benchmark level; and
(c) administering to the patient candidate a therapeutically effective amount of the compound.

5. The compound according to any one of claims 1 to 3, wherein the compound is to be administered to the subject in two daily doses.

6. The compound according to claim 3 or claim 5, wherein each dose is about 480 mg.

7. The compound according to any one of claims 3, 5 or 6, wherein the compound is to be administered to the subject as a tablet or capsule.

8. The compound according to claim 7, wherein the tablet or capsule comprises a dose of about 80 mg.

9. The compound according to any one of claims 1 to 3 or 5 to 8, wherein the interval between administrations of the compound is:

a) in the range from about 4 hours to about 16 hours; or

b) selected from the group consisting of at least about 4 hours, at least about 5 hours, at

least about 6 hours, at least about 7 hours, at least about 8 hours, at least about 9 hours, at

least about 10 hours, at least about 11 hours, at least about 12 hours, at least about 13 hours, at least about 14 hours, at least about 15 hours and at least about 16 hours; or

c) or about 12 hours.

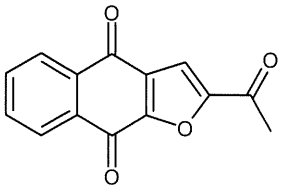
10. The compound according to any one of claims 1 to 3 or 5 to 9, wherein the compound is to be administered to the subject at a dose selected from the group consisting of about 80 mg BID, about 160 mg BID, about 320 mg BID, about 400 mg BID, about 480 mg BID, about 500 mg BID, and about 600 mg BID.

11. The compound according to any one of claims 1 to 3 or 5 to 10, wherein each dose is about 480 mg BID and the interval between administrations is about 12 hours, about 80 mg BID and the interval between administrations is about 12 hours, about 400 mg BID and the interval between administrations is about 12 hours, or about 320 mg BID and the interval between administrations is about 12 hours.

12. The compound according to any one of claims 1 to 3 or 5 to 11, wherein the compound is to be administered orally in conjunction with a fluid, preferably milk or water, on an empty stomach.

13. The compound according to claim 1, wherein the treatment further comprises detecting nuclear β-catenin expression in a patient's tissue, where such nuclear β-catenin expression is used as a biomarker for patient selection.

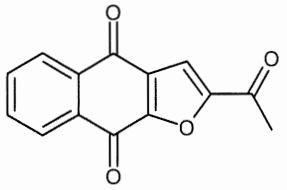
14. A first agent having the structure



or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof; and
an antimitotic agent or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof,
for use in the curative or prophylactic treatment of cancer.

15. The first agent according to claim 14, and an antimitotic agent, wherein the antimitotic agent is selected from the group consisting of paclitaxel (Abraxane/Taxol), docetaxel (taxotere), BMS-275183, xyotax, tocosal, vinorlebine, vincristine, vinblastine, vindesine, vinzolidine, etoposide (VP-16), teniposide (VM-26), ixabepilone, larotaxel, ortataxel, tesetaxel, and ispinesib; preferably is paclitaxel (Abraxane/Taxol).

16. A compound having the structure



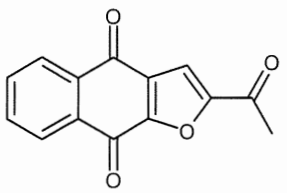
or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof, for use in the treatment of cancer, wherein the cancer is colorectal cancer, colon adenocarcinoma or rectal adenocarcinoma.

17. The compound according to claim 16, wherein the compound is to be administered to the subject in two daily doses totaling in a range from about 80 mg to about 2000 mg; preferably about 480 mg.

18. The compound according to claim 16 or claim 17, wherein the interval between administrations of the compound is in the range from about 4 hours to about 16 hours.

19. The compound according to any one of claims 1 to 6 or 11, wherein the compound is to be administered to the subject at a dose selected from the group consisting of about 80 mg BID, about 160 mg BID, about 320 mg BID, about 400 mg BID, about 480 mg BID, and about 500 mg BID.

20. A pharmaceutical composition, comprising:
a therapeutically effective amount of an active ingredient having the structure



a surfactant comprising sodium lauryl sulfate (SLS) or sodium dodecyl sulfate (SDS); Gelucire (lauroyl polyoxylglycerides); and Labrafil (linoleoyl polyoxylglycerides).

21. The pharmaceutical composition according to claim 20, consisting of, by weight, about 27.18% in the active ingredient, about 0.27% in the surfactant, about 14.51% in Gelucire, and about 58.04% in Labrafil.

22. The pharmaceutical composition according to claim 20, consisting of:

a) about 125 mg of the active ingredient, about 1.2 mg of the surfactant, about 66.8 mg of

Gelucire, and about 267 mg of Labrafil; or

b) about 80 mg of the active ingredient, about 0.8 mg of the surfactant, about 42.7 mg of Gelucire, and about 170.9 mg of Labrafil.

23. An item of manufacture comprising the pharmaceutical composition of any one of claims 20 to 22 housed in a capsule; or a capsule of size 1 or smaller.

24. The compound according to claim 3, wherein the cancer is selected from the group consisting of colorectal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma, gastric/gastroesophageal adenocarcinoma, esophageal adenocarcmoma, and adrenocorticoid carcinoma; preferably colorectal adenocarcinoma.

25. The compound according to any one of claims 1 to 2 or 5 to 6 or 9 to 12, wherein the paclitaxel is to be administered to the subject at a total weekly dose in a range from about 40 mg/m^2 to about 100 mg/m^2; preferably a total weekly dose of about 80 mg/m^2.

26. The compound according to claim 25, wherein the paclitaxel is to be administered to the subject through IV.

27. The compound according to any one of claims 1 to 3 or 5 to 12 or 25 to 26, wherein the cancer is selected from the group consisting of gastric and gastroesophageal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma, and esophageal adenocarcinoma; preferably gastric and gastroesophageal adenocarcinoma.

28. The compound according to any one of claims 1 to 3 or 5 to 12 or 25 to 26, wherein the cancer is selected from the group consisting of colorectal adenocarcinoma, breast cancer, ovarian cancer, head and neck cancer, melanoma, gastric adenocarcinoma, and adrenocorticoid carcinoma.

29. The compound according to any one of claims 1 to 3 or 5 to 12 or 25 to 28, wherein the cancer is refractory, recurrent, or/and metastatic.

30. The compound according to any one of claims 1 to 3 or 5 to 12 or 25 to 29, wherein the cancer is associated:

a) with overexpression of STATS; or

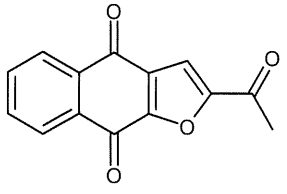
b) with nuclear β-catenin expression.

31. The compound according to any one of claims 1 to 3 or 5 to 12 or 25 to 30, the method comprising detecting a level of phosphorylated STAT3 (p-STAT3) in a patient tissue, where the level of p-STAT3 is used as a biomarker for patient selection.

32. The compound according to any one of claims 1 to 3 or 5 to 12 or 25 to 29 and 44, the method comprising detecting β-catenin expression in a patient's tissue, where such β-catenin expression is used as a biomarker for patient selection.

33. The compound according to claim 32, wherein significant β-catenin expression is detected in cell nucleus.

34. A compound having the structure

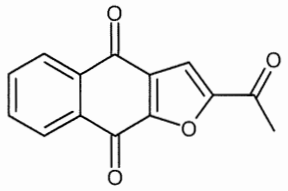


or a pharmaceutically acceptable salt, solvate, hydrate, or prodrug thereof, for use in the treatment of cancer in a patient whose β-catenin expression in cell is detected in cell nucleus.

35. The compound according to claim 34, wherein the β-catenin is at a level of medium to strong expression of β-catenin such that β-catenin is detected in 20% or more tumor cells.

36. A pharmaceutical composition, comprising:

(a) a therapeutically effective amount of an active ingredient having the structure



(b) polyoxylglycerides of which HLB is more than 10; and

(c) polyoxylglycerides of which HLB is less than 10.

37. The pharmaceutical composition according to claim 36, wherein the composition further comprises a surfactant; preferably sodium lauryl sulfate (SLS) or sodium dodecyl sulfate.

38. The pharmaceutical composition according to claim 36 or claim 37, wherein the polyoxylglycerides of which HLB is more than 10 is selected from the group consisting of lauroyl polyoxylglycerides and stearoyl polyoxylglycerides.

39. The pharmaceutical composition according to any one of claims 36 to 38, wherein the poly-oxylglycerides of which HLB is less than 10 is linoleoyl polyoxylglycerides.