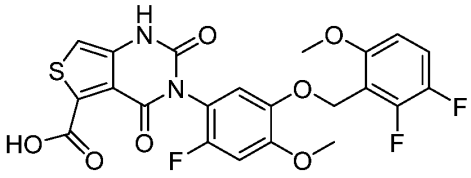
CLAIMS

1. A method of reducing the volume of menstrual blood loss in a human patient, said method comprising administering to said patient a compound represented by formula (**I**),

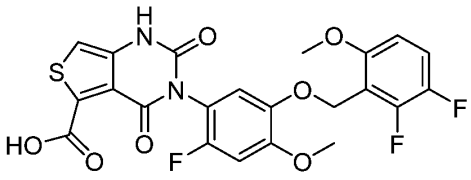


(**I**)

or a pharmaceutically acceptable salt thereof, in an amount of about 100 mg per day.

2. The method of claim 1, wherein said patient has uterine fibroids.

3. A method of treating uterine fibroids in a human patient, said method comprising administering to said patient a compound represented by formula (**I**),



(**I**)

or a pharmaceutically acceptable salt thereof, in an amount of about 100 mg per day.

4. The method of any one of claims 1-3, wherein said compound is the choline salt of formula (**I**).

5. The method of claim 4, wherein said choline salt is in a crystalline state.

6. The method of claim 5, wherein said choline salt exhibits characteristic X-ray powder diffraction peaks at about 7.1° 2θ, about 11.5° 2θ, about 19.4° 2θ, about 21.5° 2θ, about 22.0° 2θ, about 22.6° 2θ, about 23.5° 2θ, and about 26.2° 2θ.

7. The method of claim 5 or 6, wherein said choline salt exhibits ^{13}C solid-state nuclear magnetic resonance (NMR) peaks centered at about 55.5 ppm, about 57.1 ppm, about 58.7 ppm, about 69.8 ppm, about 98.1 ppm, about 110.3 ppm, about 111.6 ppm, about 113.7 ppm, about 118.0 ppm, about 145.3 ppm, about 149.8 ppm, and about 155.8 ppm.

8. The method of any one of claims 5-7, wherein said choline salt exhibits ^{19}F solid-state NMR peaks centered at about -151.8 ppm, -145.2 ppm, and -131.6 ppm.

9. The method of any one of claims 1-8, wherein said compound is orally administered to said patient.

10. The method of any one of claims 1-9, said method comprising administering add-back therapy to said patient.

11. The method of claim 10, wherein said add-back therapy is administered to said patient once daily, concurrently with said compound.

12. The method of claim 10, wherein said add-back therapy is administered to said patient once daily, prior to administration of said compound.

13. The method of claim 10, wherein said add-back therapy is administered to said patient once daily, following administration of said compound.

14. The method of claim 10, wherein said add-back therapy is administered to said patient in the form of a pharmaceutical composition comprising said compound.

15. The method of any one of claims 10-14, wherein said add-back therapy comprises an estrogen.

16. The method of claim 15, wherein said estrogen is selected from the group consisting of β17-estradiol, ethinyl estradiol, and conjugated estrogens.

17. The method of claim 16, wherein said estrogen is β17-estradiol.

18. The method of claim 17, wherein said β17-estradiol is administered to said patient at a dose of 1.0 mg/day.

19. The method of claim 17, wherein said β17-estradiol is administered to said patient at a dose of about 0.5 mg/day.

20. The method of claim 16, wherein said estrogen is ethinyl estradiol.

21. The method of claim 20, wherein said ethinyl estradiol is administered to said patient at a dose of about 5.0 µg/day.

22. The method of claim 20, wherein said ethinyl estradiol is administered to said patient at a dose of about 2.5 µg/day.

23. The method of claim 16, wherein said estrogen is a conjugated estrogen.

24. The method of claim 23, wherein said conjugated estrogen is administered to said patient at a dose of about 0.625 mg/day.

25. The method of claim 23, wherein said conjugated estrogen is administered to said patient at a dose of about 0.45 mg/day.

26. The method of claim 23, wherein said conjugated estrogen is administered to said patient at a dose of about 0.3 mg/day

27. The method of any one of claims 10-26, wherein said add-back therapy comprises a progestin.

28. The method of claim 27, wherein said progestin is selected from the group consisting of norethindrone or an ester thereof, progesterone, norgestimate, medroxyprogesterone, and drospirenone.

29. The method of claim 28, wherein said progestin is norethindrone or norethindrone acetate.

30. The method of claim 29, wherein said norethindrone or norethindrone acetate is administered to said patient at a dose of about 1.0 mg/day.

31. The method of claim 29, wherein said norethindrone or norethindrone acetate is administered to said patient at a dose of about 0.5 mg/day.

32. The method of claim 29, wherein said norethindrone or norethindrone acetate is administered to said patient at a dose of about 0.1 mg/day.

33. The method of claim 28, wherein said progestin is progesterone.

34. The method of claim 33, wherein said progesterone is administered to said patient at a dose of about 200 mg/day.

35. The method of claim 33, wherein said progesterone is administered to said patient at a dose of about 100 mg/day.

36. The method of claim 28, wherein said progestin is norgestimate.

37. The method of claim 36, wherein said norgestimate is administered to said patient at a dose of about 0.09 mg/day.

38. The method of claim 28, wherein said progestin is medroxyprogesterone.

39. The method of claim 38, wherein said medroxyprogesterone is administered to said patient at a dose of about 5 mg/day.

40. The method of claim 38, wherein said medroxyprogesterone is administered to said patient at a dose of about 2.5 mg/day.

41. The method of claim 38, wherein said medroxyprogesterone is administered to said patient at a dose of about 1.5 mg/day.

42. The method of claim 28, wherein said progestin is drospirenone.

43. The method of claim 42, wherein said drospirenone is administered to said patient at a dose of about 0.5 mg/day.

44. The method of claim 42, wherein said drospirenone is administered to said patient at a dose of about 0.25 mg/day.

45. The method of any one of claims 10-44, wherein said add-back therapy comprises about 1.0 mg of β17-estradiol and about 0.5 mg of norethindrone acetate.

46. The method of any one of claims 10-44, wherein said add-back therapy comprises about 0.5 mg of β17-estradiol and about 0.1 mg of norethindrone acetate.

47. The method of any one of claims 1-46, wherein said patient exhibits a serum concentration of β17-estradiol of less than 50 pg/ml following administration of said compound to said patient.

48. The method of claim 47, wherein said patient exhibits a serum concentration of β17-estradiol of less than 50 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

49. The method of any one of claims 1-48, wherein said patient exhibits a serum concentration of β17-estradiol of less than 20 pg/ml following administration of said compound to said patient.

50. The method of claim 49, wherein said patient exhibits a serum concentration of β17-estradiol of less than 20 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

51. The method of any one of claims 1-50, wherein said patient exhibits a serum concentration of β17-estradiol of less than 10 pg/ml following administration of said compound to said patient.

52. The method of claim 51, wherein said patient exhibits a serum concentration of E2 of less than 10 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

53. The method of any one of claims 1-52, wherein said patient exhibits amenorrhea following administration of said compound to said patient.

54. The method of claim 53, wherein said patient exhibits amenorrhea within about 2 weeks of the first administration of said compound to said patient.

55. The method of claim 53, wherein said patient exhibits amenorrhea within about 1 week of the first administration of said compound to said patient.

56. The method of any one of claims 53-55, wherein said amenorrhea is sustained for at least 7 days.

57. The method of any one of claims 53-56, wherein said amenorrhea is sustained for at least 14 days.

58. The method of any one of claims 53-57, wherein said amenorrhea is sustained for at least 28 days.

59. The method of any one of claims 1-58, wherein said patient has iron deficiency anemia.

60. The method of any one of claims 1-59, wherein said patient exhibits a serum progesterone concentration of from about 0.5 nM to about 0.7 nM following administration of said compound to said patient.

61. The method of claim 60, wherein said serum progesterone concentration of from about 0.5 nM to about 0.7 nM is sustained for from about 8 days to about 42 days.

62. The method of any one of claims 1-61, wherein said patient exhibits reduced pelvic pain following administration of said compound to said patient.

63. The method of any one of claims 1-62, wherein said patient exhibits reduced back pain following administration of said compound to said patient.

64. The method of any one of claims 1-63, wherein said patient does not exhibit a reduction in bone mineral density (BMD) of greater than 5% following administration of said compound to said patient.

65. The method of claim 64, wherein said patient does not exhibit a reduction in BMD of greater than 1% following administration of said compound to said patient.

66. The method of claim 64 or 65, wherein said BMD is assessed by dual energy X-ray absorptiometry.

67. The method of claim 66, wherein said BMD is assessed in the spine or femur of said patient.

68. The method of claim 64 or 65, wherein said BMD is assessed by comparing the concentration of bone specific alkaline phosphatase (BAP) in a sample isolated from said patient following said administration to the concentration of BAP in a sample isolated from said patient prior to said administration.

69. The method of claim 64 or 65, wherein said BMD is assessed by comparing the concentration of deoxypyridinoline (DPD) in a sample isolated from said patient following said administration to the concentration of DPD in a sample isolated from said patient prior to said administration.

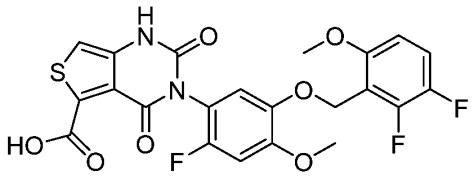
70. The method of claim 64 or 65, wherein said BMD is assessed by comparing the concentration of type I collagen C-terminal telopeptide (CTX) in a sample isolated from said patient following said administration to the concentration of CTX in a sample isolated from said patient prior to said administration.

71. The method of claim 64 or 65, wherein said BMD is assessed by comparing the concentration of procollagen 1 N-terminal peptide (P1NP) in a sample isolated from said patient following said administration to the concentration of P1NP in a sample isolated from said patient prior to said administration.

72. The method of any one of claims 1-71, wherein said compound is administered to said patient daily for about 6 weeks.

73. The method of any one of claims 1-71, wherein said compound is administered to said patient daily for 42 days.

74. A kit comprising a compound represented by formula (**I**)

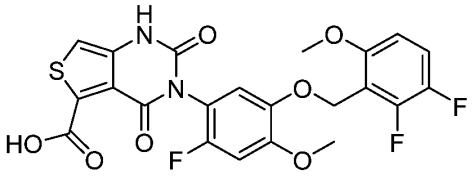


(**I**)

or a pharmaceutically acceptable salt thereof and a package insert, wherein said package insert instructs a user of said kit to perform the method of any one of claims 1-73.

75. The kit of claim 74, wherein said compound is the choline salt of formula (**I**).

76. A method of reducing the volume of menstrual blood loss in a human patient, said method comprising administering to said patient a compound represented by formula (**I**),

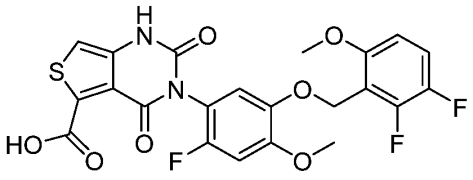


(**I**)

or a pharmaceutically acceptable salt thereof, in an amount of about 200 mg per day.

77. The method of claim 76, wherein said patient has uterine fibroids.

78. A method of treating uterine fibroids in a human patient, said method comprising administering to said patient a compound represented by formula (**I**),



(**I**)

or a pharmaceutically acceptable salt thereof, in an amount of about 200 mg per day.

79. The method of any one of claims 76-78, wherein said compound is the choline salt of formula (**I**).

80. The method of claim 79, wherein said choline salt is in a crystalline state.

81. The method of claim 80, wherein said choline salt exhibits characteristic X-ray powder diffraction peaks at about 7.1° 2θ, about 11.5° 2θ, about 19.4° 2θ, about 21.5° 2θ, about 22.0° 2θ, about 22.6° 2θ, about 23.5° 2θ, and about 26.2° 2θ.

82. The method of claim 80 or 81, wherein said choline salt exhibits ^{13}C solid-state NMR peaks centered at about 55.5 ppm, about 57.1 ppm, about 58.7 ppm, about 69.8 ppm, about 98.1 ppm, about 110.3 ppm, about 111.6 ppm, about 113.7 ppm, about 118.0 ppm, about 145.3 ppm, about 149.8 ppm, and about 155.8 ppm.

83. The method of any one of claims 80-82, wherein said choline salt exhibits ^{19}F solid-state NMR peaks centered at about -151.8 ppm, -145.2 ppm, and -131.6 ppm.

84. The method of any one of claims 76-83, wherein said compound is orally administered to said patient.

85. The method of any one of claims 76-84, said method comprising administering add-back therapy to said patient.

86. The method of claim 85, wherein said add-back therapy is administered to said patient once daily, concurrently with said compound.

87. The method of claim 85, wherein said add-back therapy is administered to said patient once daily, prior to administration of said compound.

88. The method of claim 85, wherein said add-back therapy is administered to said patient once daily, following administration of said compound.

89. The method of claim 86, wherein said add-back therapy is administered to said patient in the form of a pharmaceutical composition comprising said compound.

90. The method of any one of claims 85-89, wherein said add-back therapy comprises an estrogen.

91. The method of claim 90, wherein said estrogen is selected from the group consisting of β17-estradiol, ethinyl estradiol, and conjugated estrogens.

92. The method of claim 91, wherein said estrogen is β17-estradiol.

93. The method of claim 92, wherein said β17-estradiol is administered to said patient at a dose of about 1.0 mg/day.

94. The method of claim 92, wherein said β17-estradiol is administered to said patient at a dose of about 0.5 mg/day.

95. The method of claim 91, wherein said estrogen is ethinyl estradiol.

96. The method of claim 95, wherein said ethinyl estradiol is administered to said patient at a dose of about 5.0 µg/day.

97. The method of claim 95, wherein said ethinyl estradiol is administered to said patient at a dose of about 2.5 µg/day.

98. The method of claim 91, wherein said estrogen is a conjugated estrogen.

99. The method of claim 98, wherein said conjugated estrogen is administered to said patient at a dose of about 0.625 mg/day.

100. The method of claim 98, wherein said conjugated estrogen is administered to said patient at a dose of about 0.45 mg/day.

101. The method of claim 98, wherein said conjugated estrogen is administered to said patient at a dose of about 0.3 mg/day

102. The method of any one of claims 85-101, wherein said add-back therapy comprises a progestin.

103. The method of claim 102, wherein said progestin is selected from the group consisting of norethindrone or an ester thereof, progesterone, norgestimate, medroxyprogesterone, and drospirenone.

104. The method of claim 103, wherein said progestin is norethindrone or norethindrone acetate.

105. The method of claim 104, wherein said norethindrone or norethindrone acetate is administered to said patient at a dose of about 1.0 mg/day.

106. The method of claim 104, wherein said norethindrone or norethindrone acetate is administered to said patient at a dose of about 0.5 mg/day.

107. The method of claim 104, wherein said norethindrone or norethindrone acetate is administered to said patient at a dose of about 0.1 mg/day.

108. The method of claim 103, wherein said progestin is progesterone.

109. The method of claim 108, wherein said progesterone is administered to said patient at a dose of about 200 mg/day.

110. The method of claim 108, wherein said progesterone is administered to said patient at a dose of about 100 mg/day.

111. The method of claim 103, wherein said progestin is norgestimate.

112. The method of claim 111, wherein said norgestimate is administered to said patient at a dose of about 0.09 mg/day.

113. The method of claim 103, wherein said progestin is medroxyprogesterone.

114. The method of claim 113, wherein said medroxyprogesterone is administered to said patient at a dose of about 5 mg/day.

115. The method of claim 113, wherein said medroxyprogesterone is administered to said patient at a dose of about 2.5 mg/day.

116. The method of claim 113, wherein said medroxyprogesterone is administered to said patient at a dose of about 1.5 mg/day.

117. The method of claim 103, wherein said progestin is drospirenone.

118. The method of claim 117, wherein said drospirenone is administered to said patient at a dose of about 0.5 mg/day.

119. The method of claim 117, wherein said drospirenone is administered to said patient at a dose of about 0.25 mg/day.

120. The method of any one of claims 85-119, wherein said add-back therapy comprises about 1.0 mg of β17-estradiol and about 0.5 mg of norethindrone acetate.

121. The method of any one of claims 85-119, wherein said add-back therapy comprises about 0.5 mg of β17-estradiol and about 0.1 mg of norethindrone acetate.

122. The method of any one of claims 76-121, wherein said patient exhibits a serum concentration of β17-estradiol of less than 50 pg/ml following administration of said compound to said patient.

123. The method of claim 122, wherein said patient exhibits a serum concentration of β17-estradiol of less than 50 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

124. The method of any one of claims 76-123, wherein said patient exhibits a serum concentration of β17-estradiol of less than 20 pg/ml following administration of said compound to said patient.

125. The method of claim 124, wherein said patient exhibits a serum concentration of β17-estradiol of less than 20 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

126. The method of any one of claims 76-125, wherein said patient exhibits a serum concentration of β17-estradiol of less than 10 pg/ml following administration of said compound to said patient.

127. The method of claim 126, wherein said patient exhibits a serum concentration of E2 of less than 10 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

128. The method of any one of claims 76-127, wherein said patient exhibits amenorrhea following administration of said compound to said patient.

129. The method of claim 128, wherein said patient exhibits amenorrhea within about 2 weeks of the first administration of said compound to said patient.

130. The method of claim 128, wherein said patient exhibits amenorrhea within about 1 week of the first administration of said compound to said patient.

131. The method of any one of claims 128-130, wherein said amenorrhea is sustained for at least 7 days.

132. The method of any one of claims 128-131, wherein said amenorrhea is sustained for at least 14 days.

133. The method of any one of claims 128-132, wherein said amenorrhea is sustained for at least 28 days.

134. The method of any one of claims 76-133, wherein said patient has iron deficiency anemia.

135. The method of any one of claims 76-134, wherein said patient exhibits a serum progesterone concentration of from about 0.5 nM to about 0.7 nM following administration of said compound to said patient.

136. The method of claim 135, wherein said serum progesterone concentration of from about 0.5 nM to about 0.7 nM is sustained for from about 8 days to about 42 days.

137. The method of any one of claims 76-136, wherein said patient exhibits reduced pelvic pain following administration of said compound to said patient.

138. The method of any one of claims 76-137, wherein said patient exhibits reduced back pain following administration of said compound to said patient.

139. The method of any one of claims 76-138, wherein said patient does not exhibit a reduction in BMD of greater than 5% following administration of said compound to said patient.

140. The method of claim 139, wherein said patient does not exhibit a reduction in BMD of greater than 1% following administration of said compound to said patient.

141. The method of claim 139 or 140, wherein said BMD is assessed by dual energy X-ray absorptiometry.

142. The method of claim 141, wherein said BMD is assessed in the spine or femur of said patient.

143. The method of claim 139 or 140, wherein said BMD is assessed by comparing the concentration of BAP in a sample isolated from said patient following said administration to the concentration of BAP in a sample isolated from said patient prior to said administration.

144. The method of claim 139 or 140, wherein said BMD is assessed by comparing the concentration of DPD in a sample isolated from said patient following said administration to the concentration of DPD in a sample isolated from said patient prior to said administration.

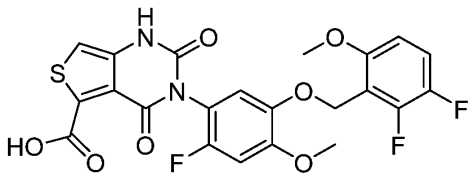
145. The method of claim 139 or 140, wherein said BMD is assessed by comparing the concentration of CTX in a sample isolated from said patient following said administration to the concentration of CTX in a sample isolated from said patient prior to said administration.

146. The method of claim 139 or 140, wherein said BMD is assessed by comparing the concentration of P1NP in a sample isolated from said patient following said administration to the concentration of P1NP in a sample isolated from said patient prior to said administration.

147. The method of any one of claims 76-146, wherein said compound is administered to said patient daily for about 6 weeks.

148. The method of any one of claims 76-146, wherein said compound is administered to said patient daily for 42 days.

149. A kit comprising a compound represented by formula (**I**)

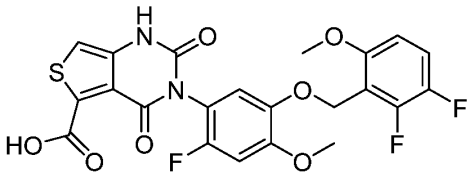


(**I**)

or a pharmaceutically acceptable salt thereof and a package insert, wherein said package insert instructs a user of said kit to perform the method of any one of claims 76-148.

150. The kit of claim 149, wherein said compound is the choline salt of formula (**I**).

151. A method of reducing the volume of menstrual blood loss in a human patient, said method comprising administering to said patient a therapeutically effective amount of a compound represented by formula (**I**)

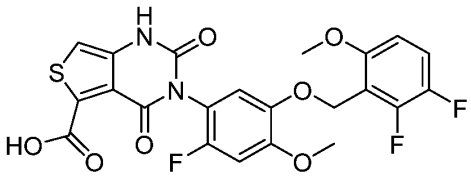


(I)

or a pharmaceutically acceptable salt thereof in combination with add-back therapy, wherein said add-back therapy comprises about 1.0 mg of β17-estradiol and about 0.5 mg of norethindrone acetate.

152. The method of claim 151, wherein said patient has uterine fibroids.

153. A method of treating uterine fibroids in a human patient, said method comprising administering to said patient a therapeutically effective amount of a compound represented by formula (**I**)



(I)

or a pharmaceutically acceptable salt thereof in combination with add-back therapy, wherein said add-back therapy comprises about 1.0 mg of β17-estradiol and about 0.5 mg of norethindrone acetate.

154. The method of any one of claims 151-153, wherein said compound is the choline salt of formula (**I**).

155. The method of claim 154, wherein said choline salt is in a crystalline state.

156. The method of claim 155, wherein said choline salt exhibits characteristic X-ray powder diffraction peaks at about 7.1° 2θ, about 11.5° 2θ, about 19.4° 2θ, about 21.5° 2θ, about 22.0° 2θ, about 22.6° 2θ, about 23.5° 2θ, and about 26.2° 2θ.

157. The method of claim 155 or 156, wherein said choline salt exhibits ^{13}C solid-state NMR peaks centered at about 55.5 ppm, about 57.1 ppm, about 58.7 ppm, about 69.8 ppm, about 98.1 ppm, about 110.3 ppm, about 111.6 ppm, about 113.7 ppm, about 118.0 ppm, about 145.3 ppm, about 149.8 ppm, and about 155.8 ppm.

158. The method of any one of claims 155-157, wherein said choline salt exhibits ^{19}F solid-state NMR peaks centered at about -151.8 ppm, -145.2 ppm, and -131.6 ppm.

159. The method of any one of claims 151-158, wherein said compound is orally administered to said patient.

160. The method of any one of claims 151-159, wherein said compound is administered to said patient at a dose of about 100 mg one or more times daily.

161. The method of claim 160, wherein said compound is administered to said patient at a dose of about 100 mg/day.

162. The method of any one of claims 151-159, wherein said compound is administered to said patient at a dose of about 200 mg one or more times daily.

163. The method of claim 162, wherein said compound is administered to said patient at a dose of about 200 mg/day.

164. The method of any one of claims 151-163, wherein said add-back therapy is administered to said patient one or more times daily.

165. The method of claim 164, wherein said add-back therapy is administered to said patient once daily, concurrently with said compound.

166. The method of claim 164, wherein said add-back therapy is administered to said patient once daily, prior to administration of said compound.

167. The method of claim 164, wherein said add-back therapy is administered to said patient once daily, following administration of said compound.

168. The method of claim 165, wherein said add-back therapy is administered to said patient in the form of a pharmaceutical composition comprising said compound.

169. The method of any one of claims 151-168, wherein said patient exhibits a serum concentration of β17-estradiol of less than 50 pg/ml following administration of said compound to said patient.

170. The method of claim 169, wherein said patient exhibits a serum concentration of β17-estradiol of less than 50 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

171. The method of any one of claims 151-170, wherein said patient exhibits a serum concentration of β17-estradiol of less than 20 pg/ml following administration of said compound to said patient.

172. The method of claim 171, wherein said patient exhibits a serum concentration of β17-estradiol of less than 20 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

173. The method of any one of claims 151-172, wherein said patient exhibits a serum concentration of β17-estradiol of less than 10 pg/ml following administration of said compound to said patient.

174. The method of claim 173, wherein said patient exhibits a serum concentration of E2 of less than 10 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

175. The method of any one of claims 151-174, wherein said patient exhibits amenorrhea following administration of said compound to said patient.

176. The method of claim 175, wherein said patient exhibits amenorrhea within about 2 weeks of the first administration of said compound to said patient.

177. The method of claim 176, wherein said patient exhibits amenorrhea within about 1 week of the first administration of said compound to said patient.

178. The method of any one of claims 175-177, wherein said amenorrhea is sustained for at least 7 days.

179. The method of any one of claims 175-178, wherein said amenorrhea is sustained for at least 14 days.

180. The method of any one of claims 175-179, wherein said amenorrhea is sustained for at least 28 days.

181. The method of any one of claims 151-180, wherein said patient has iron deficiency anemia.

182. The method of any one of claims 151-181, wherein said patient exhibits a serum progesterone concentration of from about 0.5 nM to about 0.7 nM following administration of said compound to said patient.

183. The method of claim 182, wherein said serum progesterone concentration of from about 0.5 nM to about 0.7 nM is sustained for from about 8 days to about 42 days.

184. The method of any one of claims 151-183, wherein said patient exhibits reduced pelvic pain following administration of said compound to said patient.

185. The method of any one of claims 151-184, wherein said patient exhibits reduced back pain following administration of said compound to said patient.

186. The method of any one of claims 151-185, wherein said patient does not exhibit a reduction in BMD of greater than 5% following administration of said compound to said patient.

187. The method of claim 186, wherein said patient does not exhibit a reduction in BMD of greater than 1% following administration of said compound to said patient.

188. The method of claim 186 or 187, wherein said BMD is assessed by dual energy X-ray absorptiometry.

189. The method of claim 188, wherein said BMD is assessed in the spine or femur of said patient.

190. The method of claim 186 or 187, wherein said BMD is assessed by comparing the concentration of BAP in a sample isolated from said patient following said administration to the concentration of BAP in a sample isolated from said patient prior to said administration.

191. The method of claim 186 or 187, wherein said BMD is assessed by comparing the concentration of DPD in a sample isolated from said patient following said administration to the concentration of DPD in a sample isolated from said patient prior to said administration.

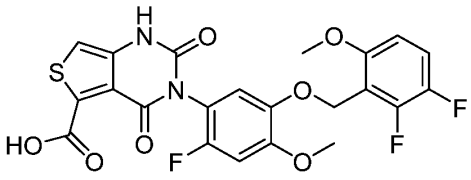
192. The method of claim 186 or 187, wherein said BMD is assessed by comparing the concentration of CTX in a sample isolated from said patient following said administration to the concentration of CTX in a sample isolated from said patient prior to said administration.

193. The method of claim 186 or 187, wherein said BMD is assessed by comparing the concentration of P1NP in a sample isolated from said patient following said administration to the concentration of P1NP in a sample isolated from said patient prior to said administration.

194. The method of any one of claims 151-193, wherein said compound and said add-back therapy are administered to said patient daily for about 6 weeks.

195. The method of any one of claims 151-193, wherein said compound and said add-back therapy are administered to said patient daily for 42 days.

196. A kit comprising a compound represented by formula (**I**)

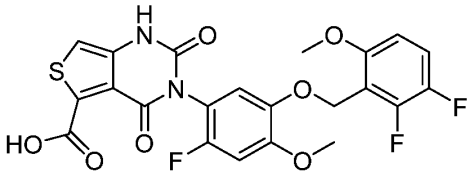


(I)

or a pharmaceutically acceptable salt thereof and a package insert, wherein said package insert instructs a user of said kit to perform the method of any one of claims 151-195.

197. The kit of claim 196, wherein said compound is the choline salt of formula (I).

198. A method of reducing the volume of menstrual blood loss in a human patient, said method comprising administering to said patient a therapeutically effective amount of a compound represented by formula (I)

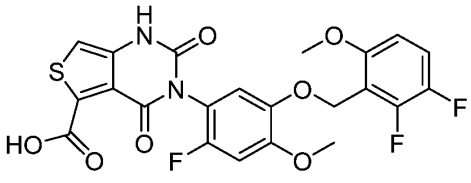


(I)

or a pharmaceutically acceptable salt thereof in combination with add-back therapy, wherein said add-back therapy comprises about 0.5 mg of β17-estradiol and about 0.1 mg of norethindrone acetate.

199. The method of claim 198, wherein said patient has uterine fibroids.

200. A method of treating uterine fibroids in a human patient, said method comprising administering to said patient a therapeutically effective amount of a compound represented by formula (I)



(I)

or a pharmaceutically acceptable salt thereof in combination with add-back therapy, wherein said add-back therapy comprises about 0.5 mg of β17-estradiol and about 0.1 mg of norethindrone acetate.

201. The method of any one of claims 198-200, wherein said compound is the choline salt of formula (I).

202. The method of claim 201, wherein said choline salt is in a crystalline state.

203. The method of claim 202, wherein said choline salt exhibits characteristic X-ray powder diffraction peaks at about 7.1° 2θ, about 11.5° 2θ, about 19.4° 2θ, about 21.5° 2θ, about 22.0° 2θ, about 22.6° 2θ, about 23.5° 2θ, and about 26.2° 2θ.

204. The method of claim 202 or 203, wherein said choline salt exhibits ^{13}C solid-state NMR peaks centered at about 55.5 ppm, about 57.1 ppm, about 58.7 ppm, about 69.8 ppm, about 98.1 ppm, about 110.3 ppm, about 111.6 ppm, about 113.7 ppm, about 118.0 ppm, about 145.3 ppm, about 149.8 ppm, and about 155.8 ppm.

205. The method of any one of claims 202-204, wherein said choline salt exhibits ^{19}F solid-state NMR peaks centered at about -151.8 ppm, -145.2 ppm, and -131.6 ppm.

206. The method of any one of claims 198-205, wherein said compound is orally administered to said patient.

207. The method of any one of claims 198-206, wherein said compound is administered to said patient at a dose of about 100 mg one or more times daily.

208. The method of claim 207, wherein said compound is administered to said patient at a dose of about 100 mg/day.

209. The method of any one of claims 198-206, wherein said compound is administered to said patient at a dose of about 200 mg one or more times daily.

210. The method of claim 209, wherein said compound is administered to said patient at a dose of about 200 mg/day.

211. The method of any one of claims 198-210, wherein said add-back therapy is administered to said patient one or more times daily.

212. The method of claim 211, wherein said add-back therapy is administered to said patient once daily, concurrently with said compound.

213. The method of claim 211, wherein said add-back therapy is administered to said patient once daily, prior to administration of said compound.

214. The method of claim 211, wherein said add-back therapy is administered to said patient once daily, following administration of said compound.

215. The method of claim 212, wherein said add-back therapy is administered to said patient in the form of a pharmaceutical composition comprising said compound.

216. The method of any one of claims 198-215, wherein said patient exhibits a serum concentration of β17-estradiol of less than 50 pg/ml following administration of said compound to said patient.

217. The method of claim 216, wherein said patient exhibits a serum concentration of β17-estradiol of less than 50 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

218. The method of any one of claims 198-217, wherein said patient exhibits a serum concentration of β17-estradiol of less than 20 pg/ml following administration of said compound to said patient.

219. The method of claim 218, wherein said patient exhibits a serum concentration of β17-estradiol of less than 20 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

220. The method of any one of claims 198-219, wherein said patient exhibits a serum concentration of β17-estradiol of less than 10 pg/ml following administration of said compound to said patient.

221. The method of claim 220, wherein said patient exhibits a serum concentration of E2 of less than 10 pg/ml within about 8 to about 15 days of the first administration of said compound to said patient.

222. The method of any one of claims 198-221, wherein said patient exhibits amenorrhea following administration of said compound to said patient.

223. The method of claim 222, wherein said patient exhibits amenorrhea within about 2 weeks of the first administration of said compound to said patient.

224. The method of claim 223, wherein said patient exhibits amenorrhea within about 1 week of the first administration of said compound to said patient.

225. The method of any one of claims 222-224, wherein said amenorrhea is sustained for at least 7 days.

226. The method of any one of claims 222-225, wherein said amenorrhea is sustained for at least 14 days.

227. The method of any one of claims 222-226, wherein said amenorrhea is sustained for at least 28 days.

228. The method of any one of claims 198-227, wherein said patient has iron deficiency anemia.

229. The method of any one of claims 198-228, wherein said patient exhibits a serum progesterone concentration of from about 0.5 nM to about 0.7 nM following administration of said compound to said patient.

230. The method of claim 229, wherein said serum progesterone concentration of from about 0.5 nM to about 0.7 nM is sustained for from about 8 days to about 42 days.

231. The method of any one of claims 198-230, wherein said patient exhibits reduced pelvic pain following administration of said compound to said patient.

232. The method of any one of claims 298-231, wherein said patient exhibits reduced back pain following administration of said compound to said patient.

233. The method of any one of claims 198-232, wherein said patient does not exhibit a reduction in BMD of greater than 5% following administration of said compound to said patient.

234. The method of claim 233, wherein said patient does not exhibit a reduction in BMD of greater than 1% following administration of said compound to said patient.

235. The method of claim 233 or 234, wherein said BMD is assessed by dual energy X-ray absorptiometry.

236. The method of claim 235, wherein said BMD is assessed in the spine or femur of said patient.

237. The method of claim 233 or 234, wherein said BMD is assessed by comparing the concentration of BAP in a sample isolated from said patient following said administration to the concentration of BAP in a sample isolated from said patient prior to said administration.

238. The method of claim 233 or 234, wherein said BMD is assessed by comparing the concentration of DPD in a sample isolated from said patient following said administration to the concentration of DPD in a sample isolated from said patient prior to said administration.

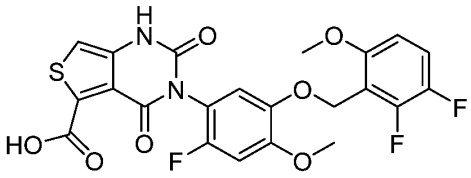
239. The method of claim 233 or 234, wherein said BMD is assessed by comparing the concentration of CTX in a sample isolated from said patient following said administration to the concentration of CTX in a sample isolated from said patient prior to said administration.

240. The method of claim 233 or 234, wherein said BMD is assessed by comparing the concentration of P1NP in a sample isolated from said patient following said administration to the concentration of P1NP in a sample isolated from said patient prior to said administration.

241. The method of any one of claims 198-240, wherein said compound and said add-back therapy are administered to said patient daily for about 6 weeks.

242. The method of any one of claims 198-240, wherein said compound and said add-back therapy are administered to said patient daily for 42 days.

243. A kit comprising a compound represented by formula (**I**)

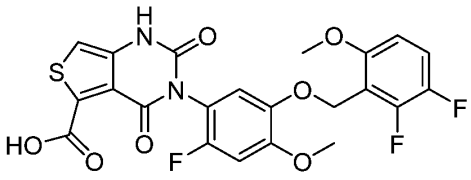


(**I**)

or a pharmaceutically acceptable salt thereof and a package insert, wherein said package insert instructs a user of said kit to perform the method of any one of claims 198-242.

244. The kit of claim 243, wherein said compound is the choline salt of formula (**I**).

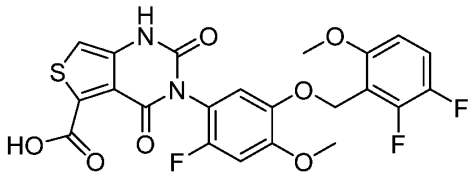
245. A method of reducing the volume of menstrual blood loss in a human patient having uterine fibroids, said method comprising administering to said patient a compound represented by formula (**I**),



(**I**)

or a pharmaceutically acceptable salt thereof, in an amount of about 100 mg per day, wherein said method further comprises administering to said patient β17-estradiol in an amount of about 1.0 mg per day and norethindrone acetate in an amount of about 0.5 mg per day.

246. A method of reducing the volume of menstrual blood loss in a human patient having uterine fibroids, said method comprising administering to said patient a compound represented by formula (**I**),



(I)

or a pharmaceutically acceptable salt thereof, in an amount of about 200 mg per day, wherein said method further comprises administering to said patient β17-estradiol in an amount of about 1.0 mg per day and norethindrone acetate in an amount of about 0.5 mg per day.

247. The method of claim 245 or 246, wherein said compound, β17-estradiol, and norethindrone acetate are administered to said patient for a treatment period of from about 4 weeks to about 52 weeks.

248. The method of claim 245 or 246, wherein said compound, β17-estradiol, and norethindrone acetate are administered to said patient for a treatment period of from about 4 weeks to about 48 weeks.

249. The method of claim 245 or 246, wherein said compound, β17-estradiol, and norethindrone acetate are administered to said patient for a treatment period of from about 4 weeks to about 24 weeks.