WHAT IS CLAIMED IS:

1. A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine, wherein the composition releases the 5-azacytidine substantially in the stomach following oral administration to a subject.

2. The composition of claim 1, which is an immediate release composition.

3. The composition of claim 1, which is non-enteric-coated.

4. The composition of claim 1, which is a tablet.

5. The composition of claim 1, which is a capsule.

6. The composition of claim 1, which further comprises an excipient selected from mannitol, microcrystalline cellulose, crospovidone, and magnesium stearate.

7. The composition of claim 1, which further comprises a permeation enhancer.

8. The composition of claim 7, wherein the permeation enhancer is d-alpha-tocopheryl polyethylene glycol 1000 succinate.

9. The composition of claim 8, wherein the d-alpha-tocopheryl polyethylene glycol 1000 succinate is present in the formulation at about 2% by weight relative to the total weight of the formulation.

10. The composition of claim 1, which is essentially free of a cytidine deaminase inhibitor.

11. The composition of claim 1, which is essentially free of tetrahydrouridine.

12. The composition of claim 1, which further comprises an additional therapeutic agent.

13. The composition of claim 1, wherein the amount of 5-azacytidine is at least about 40 mg.

14. The composition of claim 1, wherein the amount of 5-azacytidine is at least about 400 mg.

15. The composition of claim 1, wherein the amount of 5-azacytidine is at least about 1000 mg.

16. The composition of claim 1, which achieves an area-under-the-curve value of at least about 200 ng-hr/mL following oral administration to a subject.

17. The composition of claim 1, which achieves an area-under-the-curve value of at least about 400 ng-hr/mL following oral administration to a subject.

18. The composition of claim 1, which achieves a maximum plasma concentration of at least about 100 ng/mL following oral administration to a subject.

19. The composition of claim 1, which achieves a maximum plasma concentration of at least about 200 ng/mL following oral administration to a subject.

20. The composition of claim 1, which achieves a time to maximum plasma concentration of less than about 180 minutes following oral administration to a subject.

21. The composition of claim 1, which achieves a time to maximum plasma concentration of less than about 90 minutes following oral administration to a subject.

22. The composition of claim 1, which achieves a time to maximum plasma concentration of less than about 60 minutes following oral administration to a subject.

23. A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine, which releases the 5-azacytidine substantially in the stomach and achieves an area-under-the-curve value of at least about 200 ng-hr/mL following oral administration.

24. A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine, which releases the 5-azacytidine substantially in the stomach and achieves an area-under-the-curve value of at least about 400 ng-hr/mL following oral administration.

25. A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine, which releases the 5-azacytidine substantially in the stomach and achieves a maximum plasma concentration of at least about 100 ng/mL following oral administration.

26. A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine, which releases the 5-azacytidine substantially in the stomach and achieves a maximum plasma concentration of at least about 200 ng/mL following oral administration.

27. A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine, which releases the 5-azacytidine substantially in the stomach and achieves a time to maximum plasma concentration of less than about 180 minutes following oral administration.

28. A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine, which releases the 5-azacytidine substantially in the stomach and achieves a time to maximum plasma concentration of less than about 90 minutes following oral administration.

29. The composition of any one of claims 23-28, which is a single unit dosage form.

30. The composition of claim 29, which is non-enteric-coated.

31. The composition of claim 29, which is a tablet.

32. The composition of claim 29, which is a capsule.

33. A method for treating a subject having a disease associated with abnormal cell proliferation, comprising orally administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of 5-azacytidine, wherein the composition releases the 5-azacytidine substantially in the stomach following oral administration to the subject.

34. The method of claim 33, wherein the disease is myelodysplastic syndrome.

35. The method of claim 33, wherein the disease is acute myelogenous leukemia.

36. The method of claim 33, wherein the disease is non-small-cell lung cancer.

37. The method of claim 33, wherein the disease is ovarian cancer.

38. The method of claim 33, wherein the disease is pancreatic cancer.

39. The method of claim 33, wherein the disease is colorectal cancer.

40. The method of claim 33, wherein the method further comprises co-administering to the subject in need thereof an additional therapeutic agent.

41. The method of claim 33, wherein the composition is an immediate release composition.

42. The method of claim 33, wherein the composition further comprises a permeation enhancer.

43. The method of claim 42, wherein the permeation enhancer is d-alpha-tocopheryl polyethylene glycol 1000 succinate.

44. The method of claim 43, wherein the d-alpha-tocopheryl polyethylene glycol 1000 succinate is present in the formulation at about 2% by weight relative to the total weight of the formulation.

45. The method of claim 33, wherein the method further comprises not co-administering a cytidine deaminase inhibitor with the cytidine analog.

46. The method of claim 33, wherein the composition is a single unit dosage form.

47. The method of claim 33, wherein the composition is non-enteric-coated.

48. The method of claim 33, wherein the composition is a tablet.

49. The method of claim 33, wherein the composition is a capsule.

50. The method of claim 33, wherein the composition further comprises an excipient selected from mannitol, microcrystalline cellulose, crospovidone, and magnesium stearate.

51. The method of claim 33, wherein the amount of 5-azacytidine is at least about 40 mg.

52. The method of claim 33, wherein the amount of 5-azacytidine is at least about 400 mg.

53. The method of claim 33, wherein the amount of 5-azacytidine is at least about 1000 mg.

54. The method of claim 33, which achieves an area-under-the-curve value of at least about 200 ng-hr/mL following oral administration to the subject.

55. The method of claim 33, which achieves an area-under-the-curve value of at least about 400 ng-hr/mL following oral administration to the subject.

56. The method of claim 33, which achieves a maximum plasma concentration of at least about 100 ng/mL following oral administration to the subject.

57. The method of claim 33, which achieves a maximum plasma concentration of at least about 200 ng/mL following oral administration to the subject.

58. The method of claim 33, which achieves a time to maximum plasma concentration of less than about 180 minutes following oral administration to the subject.

59. The method of claim 33, which achieves a time to maximum plasma concentration of less than about 90 minutes following oral administration to the subject.

60. A pharmaceutical composition comprising a therapeutically effective amount of 5-azacytidine, wherein the composition is for treating a disease or disorder associated with abnormal cell proliferation, wherein the composition is prepared for oral administration, and wherein the composition is prepared for release of the 5-azacytidine substantially in the stomach.

61. The pharmaceutical composition of claim 60, wherein the amount of 5-azacytidine is about 40 mg, about 400 mg, or about 1000 mg.

62. The pharmaceutical composition of claim 60, wherein the composition is prepared to achieve an area-under-the-curve value of at least about 200 ng-hr/mL or 400 ng-hr/mL following oral administration.

63. The pharmaceutical composition of claim 60, wherein the composition is prepared to achieve a maximum plasma concentration of at least about 100 ng/mL or 200 ng/mL following oral administration.

64. The pharmaceutical composition of claim 60, wherein the composition is prepared to achieve a time to maximum plasma concentration of less than about 60 minutes or 90 minutes after being administered.

65. The pharmaceutical composition of any one of claims 60 to 64, wherein the composition is prepared in the form of an immediate release composition.

66. The pharmaceutical composition of any one of claims 60 to 64, wherein the composition is prepared for oral administration in combination with an additional therapeutic agent.

67. The pharmaceutical composition of any one of claims 60 to 64, wherein the disease or disorder is myelodysplastic syndrome or acute myelogenous leukemia.

68. The pharmaceutical composition of any one of claims 60 to 64, wherein the composition is a single unit dosage form.

69. The pharmaceutical composition of any one of claims 60 to 64, wherein the composition is a tablet or a capsule.

70. The pharmaceutical composition of any one of claims 60 to 64, wherein the composition further comprises an excipient selected from mannitol, microcrystalline cellulose, crospovidone, and magnesium stearate.

71. Use of 5-azacytidine for the preparation of a pharmaceutical composition for treating a disease associated with abnormal cell proliferation, wherein the composition is prepared for oral administration, and wherein the composition is prepared for release of the 5-azacytidine substantially in the stomach.

72. The use of claim 71, wherein the disease is myelodysplastic syndrome or acute myelogenous leukemia.

73. The use of claim 71 or 72, wherein the amount of 5-azacytidine is about 40 mg, about 400 mg, or about 1000 mg.

74. The use of any one of claims 71 to 73, wherein the composition is prepared for immediate release.

WHAT IS CLAIMED IS:

1. A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine, wherein the composition is a tablet comprising a non-enteric coating.

2. The composition of claim 1, which further comprises an excipient selected from mannitol, microcrystalline cellulose, crospovidone, and magnesium stearate.

3. The composition of claim 1, which further comprises a permeation enhancer.

4. The composition of claim 3, wherein the permeation enhancer is d-alpha-tocopheryl polyethylene glycol 1000 succinate.

5. The composition of claim 4, wherein the d-alpha-tocopheryl polyethylene glycol 1000 succinate is present in the composition at about 2% by weight relative to the total weight of the composition.

6. The composition of claim 1, which is essentially free of a cytidine deaminase inhibitor.

7. The composition of claim 1, which is essentially free of tetrahydrouridine.

8. The composition of claim 1, which is used in combination with an additional therapeutic agent.

9. The composition of claim 1, wherein the amount of 5-azacytidine is at least about 40 mg, at least about 100 mg, at least about 150 mg, at least about 300 mg, at least about 360 mg, at least about 400, or at least about 480 mg.

10. The composition of claim 1, which achieves an area-under-the-curve value of at least about 200 or at least about 400 ng-hr/mL following oral administration to a subject.

11. The composition of claim 1, which achieves a maximum plasma concentration of at least about 100 or at least about 200 ng/mL following oral administration to a subject.

12. The composition of claim 1, which achieves a time to maximum plasma concentration of less than about 180, less than about 90, or less than about 60 minutes following oral administration to a subject.

13. The composition of claim 1, wherein the non-enteric coating is a sugar coating, a film coating, or a compression coating.

14. The composition of claim 13, wherein the film coating is a cellulose ether polymer.

15. The composition of claim 14, wherein the cellulose ether polymer is hydroxypropyl methyl-cellulose, hydroxypropyl cellulose, or methyl-cellulose.

16. Use of a pharmaceutical composition comprising a therapeutically effective amount of 5-azacytidine, wherein the composition is a tablet comprising a non-enteric coating in the manufacture of a medicament for treating a subject having a disease associated with abnormal cell proliferation.

17. The use of claim 16, wherein the disease is myelodysplastic syndrome, acute myelogenous leukemia, chronic myelogenous leukemia, non-small-cell lung cancer, ovarian cancer, pancreatic cancer, or colorectal cancer.

18. The use of claim 16, wherein the method further comprises co-administering to the subject in need thereof an additional therapeutic agent.

19. The use of claim 16, wherein the composition further comprises a permeation enhancer.

20. The use of claim 19, wherein the permeation enhancer is d-alpha-tocopheryl polyethylene glycol 1000 succinate.

21. The use of claim 20, wherein the d-alpha-tocopheryl polyethylene glycol 1000 succinate is present in the composition at about 2% by weight relative to the total weight of the composition.

22. The use of claim 16, wherein the subject is not co-administered a cytidine deaminase inhibitor with the 5-azacytidine.

23. The use of claim 16, wherein the composition is a single unit dosage form.

24. The use of claim 16, wherein the composition further comprises an excipient selected from mannitol, microcrystalline cellulose, crospovidone, and magnesium stearate.

25. The use of claim 16, wherein the amount of 5-azacytidine is at least about 40 mg, at least about 100 mg, at least about 150 mg, at least about 300 mg, at least about 360 mg, at least about 400 mg, or at least about 480 mg per day.

26. The use of claim 16, wherein the amount of 5-azacytidine is from about 40 to about 480 mg per day.

27. The use of claim 16, which achieves an area-under-the-curve value of at least about 200 or at least about 400 ng-hr/mL following oral administration to the subject.

28. The use of claim 16, which achieves a maximum plasma concentration of at least about 100 or at least about 200 ng/mL following oral administration to the subject.

29. The use of claim 16, which achieves a time to maximum plasma concentration of less than about 180 or less than about 90 minutes following oral administration to the subject.

30. The use of claim 16, wherein the non-enteric coating is a sugar coating, a film coating, or a compression coating.

31. The use of claim 30, wherein the film coating is a cellulose ether polymer.

32. The use of claim 31, wherein the cellulose ether polymer is hydroxypropyl methyl-cellulose, hydroxypropyl cellulose, or methyl-cellulose.

33. A pharmaceutical composition comprising a therapeutically effective amount of 5-azacytidine, wherein the composition is for treating a disease or disorder associated with abnormal cell proliferation, wherein the composition is prepared for oral administration, and wherein the composition is a tablet comprising a non-enteric coating.

34. The pharmaceutical composition of claim 33, wherein the amount of 5-azacytidine is about 40 mg, about 100 mg, about 150 mg, about 300 mg, about 360 mg, about 400 mg, or about 480 mg.

35. The pharmaceutical composition of claim 33, wherein the composition is prepared to achieve an area-under-the-curve value of at least about 200 ng-hr/mL or 400 nghr/mL following oral administration.

36. The pharmaceutical composition of claim 33, wherein the composition is prepared to achieve a maximum plasma concentration of at least about 100 ng/mL or 200 ng/mL following oral administration.

37. The pharmaceutical composition of claim 33, wherein the composition is prepared to achieve a time to maximum plasma concentration of less than about 60 minutes or 90 minutes after being administered.

38. The pharmaceutical composition of any one of claims 33 to 37, wherein the composition is prepared for oral administration in combination with an additional therapeutic agent.

39. The pharmaceutical composition of any one of claims 33 to 37, wherein the disease or disorder is myelodysplastic syndrome or acute myelogenous leukemia.

40. The pharmaceutical composition of any one of claims 33 to 37, wherein the composition is a single unit dosage form.

41. The pharmaceutical composition of any one of claims 33 to 37, wherein the composition further comprises an excipient selected from mannitol, microcrystalline cellulose, crospovidone, and magnesium stearate.

42. The pharmaceutical composition of claim 33, wherein the non-enteric coating is a sugar coating, a film coating, or a compression coating.

43. The pharmaceutical composition of claim 42, wherein the film coating is a cellulose ether polymer.

44. The pharmaceutical composition of claim 43, wherein the cellulose ether polymer is hydroxypropyl methyl-cellulose, hydroxypropyl cellulose, or methyl-cellulose.