WHAT IS CLAIMED IS:

1. Use of (i) a pharmaceutical composition comprising 5-azacytidine administered orally, and (ii) at least one additional therapeutic agent, in the manufacture of a medicament for ~~A method of~~ treating a human having acute myeloid leukemia and/or myelodysplastic syndrome, wherein ~~the method comprises administering to the human~~ (i) thea~~a~~ pharmaceutical composition comprising 5-azacytidine administered orally, and (ii) the at least one additional therapeutic agent are to be administered to the human.

2. The ~~method~~ use of claim 1, wherein the at least one additional therapeutic agent comprises an FMS-like tyrosine kinase 3 (FLT3) inhibitor, an isocitrate dehydrogenase 2 (IDH2) inhibitor, an isocitrate dehydrogenase 2 (IDH1) inhibitor, and/or a B-cell lymphoma 2 (BCL2) inhibitor.

3. The ~~method~~ use of claim 2, wherein the at least one additional therapeutic agent comprises gilteritinib, midostaurin, quizartinib, enasidenib, ivosidenib, and/or venetoclax.

4. The use~~method~~ of claim 3, wherein the at least one additional therapeutic agent is gilteritinib or midostaurin.

5. The use~~method~~ of claim 3, wherein the at least one additional therapeutic agent is venetoclax.

6. The use~~method~~ of any one of claims 1-5, wherein:

(a) the 5-azacytidine and the at least one additional therapeutic agent are to be administered concomitantly; or

(b) the 5-azacytidine and the at least one additional therapeutic agent are to be administered sequentially wherein the 5-azacytidine is to be administered first.

7. The use~~method~~ of any one of claims 1-5, wherein:

(a) the 5-azacytidine and the at least one additional therapeutic agent are co-formulated as a single unit dosage form; or

(b) the 5-azacytidine and the at least one additional therapeutic agent are formulated as separate dosage forms.

8. The use~~method~~ of any one of claims 1-7, wherein:

(a) the at least one additional therapeutic agent is to be administered parenterally; or

(b) the at least one additional therapeutic agent is to be administered orally.

9. The ~~method~~use of any one of claims 1-8, wherein the 5-azacytidine is to be administered:

(a) at a dose of about 50 mg, about 60 mg, about 70 mg, about 80 mg, about 90 mg, about 100 mg, about 110 mg, about 120 mg, about 130 mg, about 140 mg, about 150 mg, about 160 mg, about 170 mg, about 180 mg, about 190 mg, about 200 mg, about 210 mg, about 220 mg, about 230 mg, about 240 mg, about 250 mg, about 260 mg, about 270 mg, about 280 mg, about 290 mg, about 300 mg, about 310 mg, about 320 mg, about 330 mg, about 340 mg, about 350 mg, about 360 mg, about 370 mg, about 380 mg, about 390 mg, about 400 mg, about 410 mg, about 420 mg, about 430 mg, about 440 mg, about 450 mg, about 460 mg, about 470 mg, about 480 mg, about 490 mg, about 500 mg, about 510 mg, about 520 mg, about 530 mg, about 540 mg, about 550 mg, about 560 mg, about 570 mg, about 580 mg , about 590 mg, or about 600 mg orally; and/or

(b) at a dose of about 200 mg; and/or

(c) at a dose of about 300 mg; and/or

(d) for the first seven, fourteen, or twenty-one days of a 28-day cycle; and/or

(e) to the human one or two times per day; and/or;

(f) in the form of a capsule or a tablet.

10. The ~~method~~ use of claim 9, wherein the 5-azacytidine is to be administered in the form of a non-enteric-coated tablet.

11. The ~~method~~ use of claim 9, wherein the 5-azacytidine is to be administered in the form of an immediate release oral composition.

12. The use~~method~~ of any one of claims 1-11, wherein the 5-azacytidine is to be administered:

(a) at a dose of about 200 mg per day for 14 days in a 28-day cycle;

(b) at a dose of about 300 mg per day for 14 days in a 28-day cycle;

(c) at a dose of about 200 mg per day for 21 days in a 28-day cycle;

(d) at a dose of about 300 mg per day for 21 days in a 28-day cycle;

(e) at a dose of about 200 mg per day for 7 days in a 28-day cycle; or

(f) at a dose of about 300 mg per day for 7 days in a 28-day cycle.

13. The use~~method~~ of any one of claims 1-11, wherein the 5-azacytidine is to be administered:

(a) daily for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, or greater than 14 days, optionally followed by a treatment dosing holiday of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, or greater than 14 days;

(b) daily for 14 or more days, optionally followed by a treatment dosing holiday of 7 or more days;

(c) for 21 or more days, optionally followed by a treatment dosing holiday of 7 or more days;

(d) for 14 days, optionally followed by a treatment dosing holiday of 14 days;

(e) for 21 or more days, followed by a treatment dosing holiday of 7 or more days; or

(f) for 14 days, followed by a treatment dosing holiday of 14 days.

14. The ~~method~~ use of claim 13, wherein at least one of steps (a), (b), (c), (d), (e), or (f) are to be repeated.

15. The ~~method~~ use of any one of claims 1-8, wherein the 5-azacytidine is to be administered:

(a) at a dose of about 300 mg daily for 14 days, followed by a treatment dosing holiday of 14 days;

(b) at a dose of about 200 mg daily for 14 days, followed by a treatment dosing holiday of 14 days;

(c) at a dose of about 300 mg daily for 21 days, followed by a treatment dosing holiday of 7 days;

(d) at a dose of about 200 mg daily, followed by a treatment dosing holiday of 7 days;

(e) at a dose of 300 mg daily for 14 days, followed by a treatment dosing holiday of 14 days;

(f) at a dose of 200 mg daily for 14 days, followed by a treatment dosing holiday of 14 days;

(g) at a dose of 300 mg daily for 21 days, followed by a treatment dosing holiday of 7 days; or

(h) at a dose of 200 mg daily, followed by a treatment dosing holiday of 7 days.

16. The use~~method~~ of claim 15, wherein at least one of steps (a), (b), (c), (d), (e), (f), (g), or (h) are to be repeated.

17. The ~~method~~ use of any one of claims 1-10, wherein the 5-azacytidine is to be administered:

(a) using a treatment cycle comprising administration of 5-azacytidine per day for 7 days in a 28-day cycle;

(b) using a treatment cycle comprising administration of 5-azacytidine per day for 14 days in a 28-day cycle; or

(c) using a treatment cycle comprising administration of 5-azacytidine per day for 21 days in a 28-day cycle.

18. The ~~method~~ use of claim 4, wherein the 5-azacytidine and the at least one additional therapeutic agent provides a synergistic effect to treat the acute myeloid leukemia or myelodysplastic syndrome.

19. The use~~method~~ of claim 4, wherein:

(a) the acute myeloid leukemia is characterized as caused by a FMS-like tyrosine kinase-3 internal tandem duplication (FLT3-ITD) mutation; and/or

(b) the 5-azacytidine is to be administered before the at least one additional therapeutic agent; and/or

(c) the 5-azacytidine and at least one additional therapeutic agent augments myeloid cell leukemia 1 (MCL-1) degradation; and/or

(d) the 5-azacytidine and at least one additional therapeutic agent increases median survival as compared to 5-azacytidine administered intravenously or subcutaneously and at least one additional therapeutic agent; and/or

(e) the 5-azacytidine and at least one additional therapeutic agent increases median survival as compared to 5-azacytidine administered intravenously or subcutaneously and at least one additional therapeutic agent by about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, about 55%, about 60%, about 65%, about 70%, about 75%, about 80%, about 85%, about 90%, about 95%, or about 100%.

20. The ~~method~~ use of claim 5, wherein the 5-azacytidine and the at least one additional therapeutic agent provides a synergistic effect to treat the acute myeloid leukemia or myelodysplastic syndrome.

21. The ~~method~~ use of claim 5, wherein:

(a) the acute myeloid leukemia is characterized as caused by a FLT3-ITD mutation; and/or

(b) the acute myeloid leukemia is resistant to treatment with the at least one additional therapeutic agent alone; and/or

(c) the 5-azacytidine is to be administered before the at least one additional therapeutic agent; and/or

(d) the acute myeloid leukemia is responsive to treatment with a FMS-like tyrosine kinase-3 (FLT3 inhibitor); and/or

(e) the acute myeloid leukemia is characterized as having an overexpression of MCL-1; and/or

(f) the 5-azacytidine primes the cancer cells for apoptosis mediated by the at least one additional therapeutic agent by downregulating the expression of MCL-1; and/or

(g) the 5-azacytidine and at least one additional therapeutic agent augments MCL-1 degradation; and/or

(h) the 5-azacytidine alters cell metabolism; and/or

(i) the 5-azacytidine causes cell cycle arrest; and/or

(j) the 5-azacytidine suppresses oxidative phosphorylation; and/or

(k) the 5-azacytidine increases expression of activating transcription factor 3 (ATF3); and/or

(l) the 5-azacytidine decreases expression of stearoyl-CoA desaturase (SCD); and/or

(m) the 5-azacytidine and at least one additional therapeutic agent increases median survival as compared to 5-azacytidine administered intravenously or subcutaneously and at least one additional therapeutic agent; and/or

(n) the 5-azacytidine and at least one additional therapeutic agent increases median survival as compared to 5-azacytidine administered intravenously or subcutaneously and at least one additional therapeutic agent by about 10%, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, about 55%, about 60%, about 65%, about 70%, about 75%, about 80%, about 85%, about 90%, about 95%, or about 100%.

22. The ~~method~~ use of any one of claims 1-10, wherein ~~the method comprises~~:

(a) ~~administering~~ the 5-azacytidine is to be administered daily to the human for 1, 2, or 3 days;

(b) ~~administering~~ the at least one additional therapeutic agent is to be administered to the human for one or more days; and

(c) ~~optionally repeating steps~~ (a) and (b) are to be optionally repeated.

23. The ~~method~~ use of any one of claims 1-10, wherein ~~the method comprises~~:

(a) ~~administering~~ the 5-azacytidine is to be administered daily to the human for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, or 14 days;

(b) ~~administering~~ the at least one additional therapeutic agent is to be administered to the human for one or more days; and

(c) ~~optionally repeating steps~~ (a) and (b) are to be optionally repeated.

24. The ~~method~~ use of any one of claims 1-10, wherein ~~the method comprises~~:

(a) ~~administering~~ the 5-azacytidine daily is to be administered to the human for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21 days;

(b) ~~administering~~ the at least one additional therapeutic agent is to be administered to the human for one or more days; and

(c) ~~optionally repeating steps~~ (a) and (b) are to be optionally repeated.

25. The ~~method~~ use of any one of claims 1-10, wherein ~~the method comprises~~:

(a) ~~administering~~ the 5-azacytidine daily is to be administered to the human for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, or 14 days of a 28-day cycle;

(b) ~~concurrently administering~~ the at least one therapeutic agent is to be concurrently administered daily to the human for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, or 28 days of a 28-day cycle; and

(c) ~~optionally repeating steps~~ (a) and (b) are to be optionally repeated.

26. The ~~method~~ use of claim 25, wherein ~~administering~~ the at least one additional therapeutic agent to be administered comprises ~~administering~~ gilteritinib, midostaurin, quizartinib, enasidenib, ivosidenib, and/or venetoclax.

27. The ~~method~~ use of any one of claims 1-10, wherein ~~the method comprises~~:

(a) ~~administering~~ the 5-azacytidine daily is to be administered to the human for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21 days of a 28-day cycle;

(b) ~~concurrently administering~~ the at least one additional therapeutic agent is to be concurrently administered daily to the human for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, or 28 days of a 28-day cycle; and

(c) ~~optionally repeating steps~~ (a) and (b) are to be optionally repeated.

28. The ~~method~~ use of claim 27, wherein ~~administering~~ the at least one additional therapeutic agent to be administered comprises ~~administering~~ gilteritinib, midostaurin, quizartinib, enasidenib, ivosidenib, and/or venetoclax.

29. The ~~method~~ use of any one of claims 1-10, wherein ~~the method comprises the sequential steps of~~:

(a) ~~administering~~ the 5-azacytidine to the human for 7 days of a 28-day cycle;

(b) ~~administering~~ the at least one additional therapeutic agent to the human for 1 day of a 28-day cycle;

(c) ~~administering~~ 5-azacytidine to the human for 6 days of a 28-day cycle;

wherein (a) to (c) are to be administered sequentially; and

(d) ~~repeating steps~~ (a) to (c) are to be repeated after 7 days of a resting period.

30. The ~~method~~ use of any one of claims 1-10, wherein ~~the method comprises the sequential steps of~~:

(a) ~~administering~~ 5-azacytidine daily to the human for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21 days of a 28-day cycle;

(b) ~~administering~~ the at least one additional therapeutic agent to the human daily for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21 days of a 28-day cycle;

(c) ~~administering~~ 5-azacytidine to the human daily for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21 days of a 28-day cycle;

wherein (a) to (c) are to be administered sequentially; and

(d) ~~optionally repeating steps~~ (a) and (c) are to be optionally repeated after 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21 days of a resting period.

31. The ~~method~~ use of any one of claims 1-30, wherein the human has acute myeloid leukemia.

32. The ~~method~~ use of any one of claims 1-30, wherein the human has myelodysplastic syndrome.

33. The ~~method~~ use of claim 32, wherein the myelodysplastic syndrome is high and very high risk myelodysplastic syndrome as defined by the Revised International Prognostic Scoring System (IPSS-R).