CLAIMS:

1. A pharmaceutical composition comprising:
about 20 mg of cedazuridine; and
about 100 mg to about 160 mg of azacitidine.

2. The pharmaceutical composition of claim 1, wherein cedazuridine is formulated for immediate release.

3. The pharmaceutical composition of claim 1 or 2, wherein at least a portion of azacitidine is formulated for enteric release.

4. The pharmaceutical composition of any one of claims 1-3, wherein azacitidine is provided as minitablets comprising an enteric coat.

5. The pharmaceutical composition of claim 4, wherein the enteric coat comprises polymethacrylate or copolymers thereof.

6. The pharmaceutical composition of claim 4 or 5, wherein the enteric coat is sensitive to pH variations in the intestine.

7. The pharmaceutical composition of any one of claims 4-6, wherein each azacitidine minitablet comprises:
about 20%-60% w/w of azacitidine, wherein the percentage by weight is relative to the total weight of the uncoated azacitidine minitablets; and
one or more pharmaceutically acceptable excipients.

8. The pharmaceutical composition of claim 7, wherein the one or more pharmaceutically acceptable excipients is selected from the group consisting of lactose monohydrate, microcrystalline cellulose, hydroxypropyl methylcellulose **(HPMC),** croscarmellose sodium, silicon dioxide, and magnesium stearate.

9. The pharmaceutical composition of any one of the preceding claims, comprising about 130 to 150 mg of azacitidine.

10. The pharmaceutical composition of any one of claims 1-8, comprising about 100 to 120 mg of azacitidine

11. The pharmaceutical composition of any one of claims 1-8, comprising about 120, 124, 128, 132, 136, 140, 144, 148, 152, or 160 mg of azacitidine.

12. The pharmaceutical composition of any one of the preceding claims, wherein the cedazuridine is uncoated and in the form of minitablets, a tablet, powder, blend, granules, or pellets.

13. A capsule comprising:

one or more azacitidine minitablets formulated for modified release, comprising about 100 mg to about 160 mg of azacitidine, pharmaceutically acceptable excipients, and an enteric coat; and

immediate release cedazuridine in a form of uncoated powder or blends, comprising about 20 mg of cedazuridine and pharmaceutically acceptable excipients.

14. The capsule of claim 13, comprising about 130 to 150 mg of azacitidine.

15. The capsule of claim 13, comprising about 100 to 120 mg of azacitidine.

16. The capsule of claim 13, comprising about 120, 124, 128, 132, 136, 140, 144, 148, 152, or 160 mg of azacitidine.

17. Use of the pharmaceutical composition according to any one of claims 1-12, or a capsule according to any one of claims 13-16, in the manufacture of medicament for the treatment of cancer.

18. Use of about 20 mg of cedazuridine in the manufacture of a medicament for the treatment of cancer wherein the medicament is to be administered with about 100 mg to about 160 mg of azacitidine.

19. Use of about 100 mg to about 160 mg of azacitidine in the manufacture of a medicament for the treatment of cancer, wherein the medicament is to be administered with about 20 mg of cedazuridine.

20. The use of any one of claims 17-19, wherein the cancer is leukemia.

21. The use of any one of claims 17-19, wherein the cancer is selected from previously treated or untreated, de novo or secondary myelodysplastic syndromes (MDS), previously treated. or untreated, de novo or secondary chronic myelomonocytic leukemia (CMML), acute myeloid leukemia (ArviL) and chronic myeloid leukemia (CML), malignant peripheral nerve sheath tumors (MPNST), neurological cancer, breast cancer, hormone receptor positive tumor, head and neck cancer, primary central chondrosarcoma. myeloproliferative neoplasm (MPN), recurrent B-cell non-Hodgkin lymphoma, recurrent diffuse large B-cell lymphoma, recurrent Hodgkin lymphoma, relapsed/refractory multiple myeloma (RRMM), metastatic colorectal cancer (mCRCi, metastatic castration-resistant prostate cancer (mCRPC), and lung cancer.

22. The use of any one of claims 17-19, wherein the cancer is selected from previously treated or untreated, de novo or secondary myelodysplastic syndromes (MDS), and previously treated or untreated, de novo or secondary chronic myelomonocytic leukemia (CMML), acute myeloid leukemia (AML) or chronic myeloid leukemia (CML).

23. The use of any one of claims 17-22, further comprising administering another therapeutic agent.

24. The use of claim 23 wherein the another therapeutic agent is one or more selected from the list consisting of: ADI-PEG 20, AMG-176, APG-115, APR-246, avelumab, bendamustine, bisantrene, brentuximab vedotin, capecitabine, CB-839, cisplatin, CS-01, cusatuzumab, cyclophosphamide, cytarabine,

dasatinib, daunorubicin, DCLL9718S, decitabine, deferasirox, dexamethasone, durvalumab, eltrombopag, enasidenib, entinostat, entrectinib, enzalutamide, epacadostat, erythropoietin, etoposide, evorpacept, filgrastim, fludarabine phosphate, flumatinib, gemcitabine, gemtuzumab ozogamicin, gilteritinib, GM-CSP, GSK2879552, HMPL-523, homoharringtonine, IBI188, ibrutinib, idarubicin, itacitinib, ivosidenib,jaktinib, KPT-8602, LDE255, lenalidomide, lirilumab, LP-108, magrolimab, MAX-40279, mitoxantrone, mitoxantrone liposome, mocetinostat, moxifloxacin, nivolumab, olutasidenib, omacetaxine, oxaliplatin, paclitaxel, pembrolizumab, pevonedistat, pinometostat, pracinostat, quizartinib, revlimid, rigosertib, rituximab, romidepsin, RP7214, S64315, S65487, sabatolimab, seclidemstat, selumetinib, siremadlin, sirolimus, SL-401, SNDX-5613, sorafenib, talazoparib, tamibarotene, tolinapant, trastuzumab, tucidinostat, tyrosine kinase inhibitor, uproleselan, velcade, venetoclax, vincristine, visilizumab, vorinostat, and vosaroxin.

25. The use of any one of claims 17-19 wherein about 20 mg of cedazuridine; and about 100 mg to about 160 mg of azacitidine is to be administered to a patient.

26. The use of claim 25, wherein cedazuridine and azacitidine are to be administered together.

27. The use claim 25 or 26, wherein cedazuridine and azacitidine are formulated into a fixed dose combination.

28. The use of claim 25, wherein cedazuridine and azacitidine are to be administered separately.

29. The use of any one of claims 25-28, wherein cedazuridine is formulated for immediate release.

30. The use of any one of claims 25-29, wherein at least a portion of azacitidine is formulated for enteric release.

31. The use of any one of claims 25-30, wherein azacitidine is provided as minitablets comprising an enteric coat.

32. The use of claim 31, wherein the enteric coat comprises polymethacrylate or copolymers thereof.

33. The use of claim 31 or 32, wherein the enteric coat is sensitive to pH variations in the intestine.

34. The use of any one of claims 25-33, wherein the cancer is leukemia.

35. The use of any one of claims 25-34, wherein the cancer is selected from previously treated or untreated, de novo or secondary myelodysplastic syndromes CMDS), previously treated or untreated, de novo or secondary chronic myelomonocytic leukemia (CMML), acute myeloid leukemia (AML) and chronic myeloid leukemia (CML), malignant peripheral nerve sheath tumors (MPNST), neurological cancer, breast cancer, hormone receptor positive tumor, head and neck cancer, primary central chondrosarcoma, myeloproliferative neoplasm (MPN), recurrent B-cell non-Hodgkin lymphoma, recurrent diffuse large R-cell lymphoma, recurrent Hodgkin lymphoma, relapsed/refractory multiple myeloma (RRMM), metastatic colorectal cancer (mCRC), metastatic castration-resistant prostate cancer (mCRPC), and lung cancer.

36. The use of any one of claims 25-34, wherein the cancer is selected from previously treated or untreated, de novo or secondary myelodysplastic syndromes (MDS), previously treated or untreated, de novo or secondary chronic myelomonocytic leukemia (CMML), acute myeloid leukemia (AML) chronic myeloid leukemia (CML).

37. A pharmaceutical composition in the form of a fixed dose combination comprising:
about 20 mg of cedazuridine; and
about 100 mg to about 160 mg of azacitidine.

38. The pharmaceutical composition of claim 37, wherein cedazuridine is formulated for immediate release.

39. The pharmaceutical composition of claim 37 or 38, wherein at least a portion of azacitidine is formulated for enteric release.

40. The pharmaceutical composition of any one of claims 37-39, wherein azacitidine is provided as minitablets comprising an enteric coat.

41. The pharmaceutical composition of claim 40, wherein the enteric coat comprises polymethacrylate or copolymers thereof.

42. The pharmaceutical composition of claim 40 or 41, wherein the enteric coat is sensitive to pH variations in the intestine.

43. The pharmaceutical composition of any one of claims 40-42, wherein each azacitidine minitablet comprises:
about 20%-60% w/w of azacitidine, wherein the percentage by weight is relative to the total weight of the uncoated azacitidine minitablets; and
one or more pharmaceutically acceptable excipients.

44. The pharmaceutical composition of claim 43, wherein the one or more pharmaceutically acceptable excipients is selected from the group consisting of lactose monohydrate, microcrystalline cellulose, hydroxypropyl methylcellulose (HPMC), croscarmellose sodium, silicon dioxide, and magnesium stearate.

45. The pharmaceutical composition of claims 37-44, comprising about 130 to 150 mg of azacitidine.

46. The pharmaceutical composition of any one of claims 37-44, comprising about 120, 124, 128, 132, 136, 140, 144, 148, 152, or 160 mg of azacitidine.

47. The pharmaceutical composition of any one of claims 37-46, wherein the cedazuridine is uncoated and in the form of minitablets, a tablet, powder, blend, granules, or pellets.