azacytosine (Fazarabine or ara-AC); 6-azacytidine (6-aza-CR); 5,6-dihydro-5-azacytidine (dH-aza-CR); N^4-pentyloxycarbonyl-5'-deoxy-5-fluorocytidine (Capecitabine); N^4-octadecyl-cytarabine; elaidic acid cytarabine; or their derivatives or related analogs.

[0017] Certain embodiments herein provide compositions that are single unit dosage forms comprising a cytidine analog. Certain embodiments herein provide compositions that are non-enteric-coated. Certain embodiments herein provide compositions that are tablets comprising a cytidine analog. Certain embodiments herein provide compositions that are capsules comprising a cytidine analog. In certain embodiments, the single unit dosage forms optionally further contain one or more excipients. In certain embodiments, the tablets optionally further contain one or more excipients. In other embodiments, the capsules optionally further contain one or more excipients. In certain embodiments, the composition is a tablet that effects an immediate release of the API upon oral administration. In other embodiments, the composition is a tablet that effects a controlled release of the API substantially in the stomach. In other embodiments, the composition is a tablet that effects a controlled release of the API substantially in the stomach and the upper intestine. In certain embodiments, the composition is a capsule that effects an immediate release of the API upon oral administration. In other embodiments, the composition is a capsule that effects a controlled release of the API substantially in the stomach. In other embodiments, the composition is a capsule that effects a controlled release of the API substantially in the stomach and the upper intestine. In particular embodiments, the tablet contains a drug core that comprises a cytidine analog, and optionally further contains a coating of the drug core, wherein the coating is applied to the drug core using an aqueous solvent, such as, for example, water, or non-aqueous solvent, such as, for example ethanol.

[0018] Certain embodiments herein provide methods of making formulations of cytidine analogs intended for oral delivery. Further provided are articles of manufacture containing packaging material, an oral formulation of a cytidine analog, and a label that indicates that the formulation is for the treatment, prevention, or management of certain diseases or disorders including, *e.g.*, a cancer, a disorder related to abnormal cell proliferation, a solid tumor, a hematologic disorder, or an immune disorder.

[0018a] In one aspect, there is provided use of ~~a pharmaceutical composition comprising~~ 5-azacytidine, or a pharmaceutically acceptable hydrate thereof, and at least one pharmaceutically acceptable excipient~~, and at least one additional therapeutic agent comprising a platinum agent~~ in the manufacture of a medicament for

treating a subject having non-small cell lung cancer, wherein the ~~pharmaceutical composition comprising the 5-azacytidine, or a pharmaceutically acceptable hydrate thereof, the at least one pharmaceutically acceptable excipient and the at least one additional therapeutic agent comprising a platinum agent are to be administered orally~~treating comprises the oral administration of the medicament and the administration of at least one additional therapeutic agent comprising a platinum agent.

[0019] Certain embodiments herein provide methods of using the formulations provided herein to treat, prevent, or manage diseases or disorders including, *e.g.*, cancer, disorders related to abnormal cell proliferation, solid tumors, hematologic disorders, or immune disorders. In certain embodiments, the formulations of cytidine analogs are orally

WHAT IS CLAIMED IS:

1. Use of ~~a pharmaceutical composition comprising~~ 5-azacytidine, or a pharmaceutically acceptable hydrate thereof, and at least one pharmaceutically acceptable excipient~~, and at least one additional therapeutic agent comprising a platinum agent~~ in the manufacture of a medicament for treating a subject having non-small cell lung cancer, wherein the ~~pharmaceutical composition comprising the 5-azacytidine, or a pharmaceutically acceptable hydrate thereof, the at least one pharmaceutically acceptable excipient and the at least one additional therapeutic agent comprising a platinum agent are to be administered orally~~treating comprises the oral administration of the medicament and the administration of at least one additional therapeutic agent comprising a platinum agent.

2. The use of claim 1, wherein the non-small cell lung cancer is a relapsed or refractory non-small cell lung cancer.

3. The use of claim 1, wherein the additional therapeutic agent is carboplatin.

4. The use of any one of claims 1 to 3, wherein ~~the use~~treating the subject comprises the sequential steps of:

(i) administration of the 5-azacytidine to the subject for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, or 21 days; and

(ii) administration of the additional therapeutic agent to the subject for one or more days.

5. The use of claim 4, wherein the additional therapeutic agent is to be administered parenterally.

6. The use of claim 4, wherein the additional therapeutic agent is to be administered orally.

7. The use of any one of claims 4 to 6, wherein step (ii) further comprises the 5-azacytidine to be administered orally for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, or 14 days.

8. The use of any one of claims 4 to 6, wherein ~~the use~~treating the subjct comprises the sequential steps of:

(i) administration of the 5-azacytidine to the subject for 7 days;

(ii) administration of the additional therapeutic agent to the subject for 1 day;

(iii) administration of the 5-azacytidine to the subject for 6 days; and

(iv) repeating steps (i) to (iii) after 7 days of resting period.

9. The use of any one of claims 4 to 6, wherein ~~the use~~treating the subject comprises the sequential steps of:

(i) administration of the 5-azacytidine to the subject for 7 days;

(ii) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;

(iii) administration of the 5-azacytidine to the subject for 6 days; and

(iv) repeating steps (i) to (iii) after 7 days of resting period.

10. The use of any one of claims 4 to 6, wherein ~~the use~~ treating the subject comprises the sequential steps of:

(i) administration of the 5-azacytidine to the subject for 7 days;

(ii) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;

(iii) administration of the 5-azacytidine to the subject for 6 days;

(iv) administration of the additional therapeutic agent to the subject for 1 day; and

(v) repeating steps (i) to (iv) after 6 days of resting period.

11. The use of any one of claims 4 to 6, wherein ~~the use~~treating the subject comprises the sequential steps of:

(i) administration of the 5-azacytidine to the subject for 7 days;

(ii) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;

(iii) administration of the 5-azacytidine to the subject for 6 days;

(iv) administration of the additional therapeutic agent to the subject for 1 day;

(v) after 6 days of resting period, administering the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;

(vi) administration of the 5-azacytidine to the subject for 6 days; and

(vii) repeating steps (ii) to (vi).

12. The use of any one of claims 1 to 3, wherein ~~the use~~ treating the subject comprises administration of the 5-azacytidine to the subject for at least 1, at least 2, at least 3, at least 4, at least 5, at least 6, or at least 7 days, before administration of the additional therapeutic agent to the subject.

13. The use of claim 12, wherein the additional therapeutic agent is to be administered parenterally for one or more days.

14. The use of claim 12, wherein the additional therapeutic agent is to be administered orally for one or more days.

15. The use of any one of claims 1 to 14, wherein the ~~pharmaceutical composition~~medicament comprising the 5-azacytidine is a tablet.

16. The use of any one of claims 1 to 14, wherein the ~~pharmaceutical composition~~ medicament comprising the 5-azacytidine is a capsule.

17. The use of any one of claims 1 to 16, wherein the ~~pharmaceutical composition~~ medicament comprises about 100 mg, about 200 mg, about 300 mg, about 400 mg, about 500 mg, or about 600 mg of the 5-azacytidine.

18. The use of claim 17 wherein the ~~pharmaceutical composition~~ medicament comprises about 200 mg of the 5-azacytidine.

19. The use of claim 17, wherein the ~~pharmaceutical composition~~medicament comprises about 300 mg of the 5-azacytidine.

20. The use of any one of claims 1 to 19, wherein the subject is a human.

21. The use of any one of claims 4 to 6, wherein ~~the use~~treating the subject comprises the sequential steps of:
(i) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;
(ii) administration of the 5-azacytidine to the subject for 13 days; and
(iii) repeating steps (i) and (ii) after 7 days of resting period.

22. The use of any one of claims 4 to 6, wherein ~~the use~~treating the subject comprises the sequential steps of:
(i) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;
(ii) administration of the 5-azacytidine to the subject for 20 days; and
(iii) repeating steps (i) and (ii).

23. The use of any one of claims 4 to 6, wherein ~~the use~~treating the subject comprises the sequential steps of:
(i) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;
(ii) administration of the 5-azacytidine to the subject for 6 days;
(iii) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;
(iv) administration of the 5-azacytidine to the subject for 6 days;
(v) repeating steps (i) to (iv) after 7 days of resting period.

24. The use of any one of claims 4 to 6, wherein ~~the use~~treating the subject comprises the sequential steps of:
(i) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;
(ii) administration of the 5-azacytidine to the subject for 6 days;
(iii) administration of the 5-azacytidine and the additional therapeutic agent to the subject for 1 day;
(iv) administration of the 5-azacytidine to the subject for 13 days;
(v) repeating steps (i) to (iv).