CLAIMS

1. Use of an Fms-like tyrosine kinase (FLT3) inhibitor, a stereoisomer thereof, a tautomer thereof, or a pharmaceutically acceptable salt or solvate thereof in combination with a hypomethylating agent (HMA) in the manufacture of a medicament for treating acute myeloid leukemia (AML), wherein the FLT3 inhibitor is 5-chloro-N-(3-cyclopropyl-5-(((3R, 5S)-3,5-dimethylpiperazin-1-yl)methyl)phenyl)-4-(6-methyl-1H-indol-3-yl)pyrimidin-2-amine.

2. The use of claim 1, wherein the HMA is any one selected from 4-amino-1-β-D-ribofuranosyl-1,3,5-triazin-2(1H)-one, 4-amino-1-((2R,4R,5R)-4-hydroxy-5-(hydroxymethyl)tetrahydrofuran-2-yl)-1,3,5-triazin-2(1H)-one, or a pharmaceutically acceptable salt or hydrate thereof.

3. The use of claim 1, wherein the HMA is 4-amino-1-β-D-ribofuranosyl-1,3,5-triazin-2(1H)-one.

4. The use of claim 1, wherein the HMA is 4-amino-1-((2R,4R,5R)-4-hydroxy-5-(hydroxymethyl)tetrahydrofuran-2-yl)-1,3,5-triazin-2(1H)-one.

5. The use of claim 1, wherein the AML is AML with FLT3 mutations.

6. The use of claim 1 or 5, wherein the AML is mutant FLT3 polynucleotide-positive AML, FLT3 internal tandem duplication (ITD)-positive AML, or AML with FLT3 point mutations.

7. The use of claim 1, wherein the AML has a mutation in a tyrosine kinase domain (TKD) of an FLT3 amino acid sequence (FLT3-TKD).

8. The use of claim 7, wherein the FLT3-TKD mutation further comprises an internal tandem duplication (ITD).

9. The use of claim 7, wherein the FLT3-TKD mutation comprises any mutation selected from FLT3(D835Y), FLT3(F691L), FLT3(F691L/D835Y), FLT3(ITD/D835Y), FLT3(ITD/F691L), and a combination thereof.

10. The use of claim 1, wherein the FLT3 inhibitor or a pharmaceutically acceptable salt or solvate thereof is to be administered with the HMA or a pharmaceutically acceptable salt or solvate thereof simultaneously, sequentially, in reverse order, or individually.

11. The use of claim 1, wherein the FLT3 inhibitor and the HMA or a pharmaceutically acceptable salt or solvate thereof are in a therapeutically effective amount, respectively.

12. A pharmaceutical combination comprising a therapeutically effective amount of 5-chloro-N-(3-cyclopropyl-5-(((3R, 5S)-3,5-dimethylpiperazin-1-yl)methyl)phenyl)-4-(6-methyl-1H-indol-3-yl)pyrimidin-2-amine, or a pharmaceutically acceptable salt, solvate, stereoisomer or prodrug thereof, and a therapeutically effective amount of hypomethylating agent (HMA) or a pharmaceutically acceptable salt or solvate thereof in at least one pharmaceutical composition.

13. The pharmaceutical combination of claim 12, wherein the HMA is any one selected from 4-amino-1-β-D-ribofuranosyl-1,3,5-triazin-2(1H)-one, 4-amino-1-((2R,4R,5R)-4-hydroxy-5-(hydroxymethyl)tetrahydrofuran-2-yl)-1,3,5-triazin-2(1H)-one, and a pharmaceutically acceptable salt or hydrate thereof.

14. The pharmaceutical combination of claim 12, wherein the HMA is 4-amino-1-β-D-ribofuranosyl-1,3,5-triazin-2(1H)-one.

15. The pharmaceutical combination of claim 12, wherein the HMA is 4-amino-1-((2R,4R,5R)-4-hydroxy-5-(hydroxymethyl)tetrahydrofuran-2-yl)-1,3,5-triazin-2(1H)-one.

16. The pharmaceutical combination of claim 12, wherein the AML is AML with FLT3 mutations.

17. The pharmaceutical combination of claim 12 or 16, wherein the AML is mutant FLT3 polynucleotide-positive AML, FLT3 internal tandem duplication (ITD)-positive AML, or AML with FLT3 point mutations.

18. The pharmaceutical combination of claim 12, wherein the AML has a mutation in a tyrosine kinase domain (TKD) of an FLT3 amino acid sequence (FLT3-TKD).

19. The pharmaceutical combination of claim 18, wherein the FLT3-TKD mutation further comprises an internal tandem duplication (ITD).

20. The pharmaceutical combination of claim 18, wherein the FLT3-TKD mutation comprises any mutation selected from FLT3(D835Y), FLT3(F691L), FLT3(F691L/D835Y), FLT3(ITD/D835Y), FLT3(ITD/F691L), and a combination thereof.

21. The pharmaceutical combination of claim 12, wherein the FLT3 inhibitor or a pharmaceutically acceptable salt or solvate thereof is to be administered with the HMA or a pharmaceutically acceptable salt or solvate thereof simultaneously, sequentially, in reverse order, or individually.