Claims

[Claim 1] A method of treating an LSD1-related disease or disorder in a patient in need, the method comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient on an administration schedule comprising daily dosing for one week, followed by a resting period of one week.

[Claim 2] The method of Claim 1, wherein the administration schedule is based on a 2-week cycle, and the cycle is performed once or repeated two or more times.

[Claim 3] The method of Claim 1, wherein 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof is administered once per day for one week.

[Claim 4] The method of Claim 1, wherein 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof is administered orally.

[Claim 5] A method of treating an LSD1-related disease in a patient in need, the method comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient on an administration schedule of daily dosing for two weeks followed by a resting period for one week.

[Claim 6] The method of Claim 5, wherein the administration schedule is based on a 3-week cycle, and the cycle is performed once or repeated two or more times.

[Claim 7] The method of Claim 5, wherein 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof is administered once per day for two weeks.

[Claim 8] The method of Claim 5, wherein 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof is administered orally.

[Claim 9] A method of treating acute myeloid leukemia (AML) in a patient in need, the method comprising administering an effective amount of

4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient as a single agent administered once daily on specific days during a 28-day cycle.

[Claim 10] The method of Claim 9, wherein 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof is administered daily for one week, followed by a resting period of one week.

[Claim 11] A method of treating acute myeloid leukemia (AML) in a patient in need, the method comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient as a single agent administered once daily on specific days during a 21-day cycle.

[Claim 12] The method of Claim 11, wherein 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof is administered daily for two weeks, followed by a resting period of one week.

[Claim 13] A method of treating acute myeloid leukemia (AML) in a patient in need, the method comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient on specific days during a 28-day cycle, in combination with all-trans retinoic acid (ATRA) twice daily.

[Claim 14] The method of Claim 13, wherein 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof is administered daily for one week, followed by a resting period of one week.

[Claim 15] A method of treating acute myeloid leukemia (AML) in a patient in need, the method comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient on specific days during a 21-day cycle , in combination with all-trans retinoic acid (ATRA) twice daily.

[Claim 16] The method of Claim 15, wherein

4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof is administered daily for two weeks, followed by a resting period of one week.

[Claim 17] A method of reducing the risk of recurrence of acute myeloid leukemia (AML) or death for a patient diagnosed with AML, comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient on an administration schedule comprising daily dosing for one week, followed by a resting period of one week.

[Claim 18] A method of reducing the risk of recurrence of acute myeloid leukemia (AML) or death for a patient diagnosed with AML, comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient on an administration schedule comprising daily dosing for two weeks, followed by a resting period of one week.

[Claim 19] A method of reducing the risk of recurrence of acute myeloid leukemia (AML) or death for a patient diagnosed with AML, comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient on an administration schedule comprising daily dosing for one week, followed by a resting period of one week, in combination with all-trans retinoic acid (ATRA) twice daily.

[Claim 20] A method of reducing the risk of recurrence of acute myeloid leukemia (AML) or death for a patient diagnosed with AML, comprising administering an effective amount of 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof to the patient on an administration schedule comprising daily dosing for two weeks, followed by a resting period of one week, in combination with all-trans retinoic acid (ATRA) twice daily.

[Claim 21] The method of any one of claims 17-20, wherein the risk of recurrence of AML or death is reduced by at least about 5%, at least about 10%, at least about 15%, at least about 20%, or at least about 25%.

[Claim 22] Use of a compound comprising

4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof for the manufacture of a medicament for treating acute myeloid leukemia (AML), wherein the medicament is prepared to be administered on an administration schedule comprising daily dosing for one week, followed by a resting period of one week.

[Claim 23] Use of a compound comprising 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof for the manufacture of a medicament for treating acute myeloid leukemia (AML), wherein the medicament is prepared to be administered on an administration schedule comprising daily dosing for two weeks, followed by a resting period of one week.

[Claim 24] Use of a compound comprising 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof for the manufacture of a medicament for treating acute myeloid leukemia (AML), wherein the medicament is prepared to be administered on an administration schedule comprising daily dosing for one week, followed by a resting period of one week, in combination with all-trans retinoic acid (ATRA) twice daily.

[Claim 25] Use of a compound comprising 4-[5-[(3S)-3-aminopyrrolidine-1-carbonyl]-2-[2-fluoro-4-(2-hydroxy-2-methyl-propyl)phenyl]phenyl]-2-fluoro-benzonitrile or a salt thereof for the manufacture of a medicament for treating acute myeloid leukemia (AML), wherein the medicament is prepared to be administered on an administration schedule comprising daily dosing for two weeks, followed by a resting period of one week, in combination with all-trans retinoic acid (ATRA) twice daily.