Claims

[Claim 1] A method of treating a patient with schizophrenia or bipolar I disorder comprising:
administering intramuscularly to the patient an injectable preparation comprising aripiprazole or a salt thereof wherein the patient is administered the injectable preparation about once every two months.

[Claim 2] The method according to claim 1, wherein the administration of the injectable preparation results in a total amount of aripiprazole ranging from about 650 mg to about 1200 mg to the patient every two months.

[Claim 3] The method according to claim 2, wherein the administration of the injectable preparation results in the total amount of aripiprazole of about 960 mg to the patient every two months.

[Claim 4] The method according to any one of claims 1 to 3, wherein the about once every two months comprises about once every 42 days to 70 days.

[Claim 5] The method according to claim 4, wherein the once every two months comprises once every 54 days to 58 days.

[Claim 6] The method according to any one of claims 1 to 5, wherein the patient has schizophrenia.

[Claim 7] The method according to any one of claims 1 to 5, wherein the patient has bipolar I disorder.

[Claim 8] The method according to any one of claims 1 to 7, wherein administering intramuscularly to the patient is at a gluteal muscle.

[Claim 9] The method according to any one of claims 1 to 8, wherein the injectable preparation further comprises: water, and a suspending agent comprising polyvinylpyrrolidone, polyethylene glycol, and carboxymethylcellulose or a salt thereof, wherein aripiprazole or a salt thereof has a mean primary particle diameter ranging from about 0.5 μm to about 30 μm and the concentration of aripiprazole or a salt thereof ranges from about 200 mg/mL to about 600 mg/mL.

[Claim 10] The method according to any one of claims 1 to 8, wherein the injectable preparation further comprises: water for injection, and a suspending agent comprising polyvinylpyrrolidone, polyethylene glycol, and carboxymethylcellulose or a salt thereof, wherein the aripiprazole or a salt thereof is aripiprazole monohydrate, the aripiprazole monohydrate has a mean primary particle diameter ranging from about 2 μm to about 5 μm, and the concentration of aripiprazole in the injectable preparation is about 300 mg/mL which is calculated based on

the anhydrous form of aripiprazole.

[Claim 11] The method according to any one of claims 1 to 10, wherein an area under the concentration-time curve (AUC) of aripiprazole from time zero to 56 days postdose following a plurality of administration of the injectable preparation is substantially equal to a twofold AUC of aripiprazole from time zero to 28 days postdose following a plurality of administration of an aripiprazole intramuscular (IM) depot formulation such as Abilify Maintena(R) about once every one month (4 weeks or 28 days), e.g., as shown in Figure 2.

[Claim 12] The method according to any one of claims 1 to 10, further comprising administering orally to the patient a solid dosage form comprising aripiprazole or a salt thereof, wherein the injectable preparation and the solid dosage form are administered to the patient on a first day, and the solid dosage form is administered for consecutive 5 to 15 days from the first day.

[Claim 13] A method of treating a patient with schizophrenia or bipolar I disorder comprising:
administering to the patient at a gluteal muscle an injectable preparation comprising aripiprazole or a salt thereof,
wherein the patient is administered the injectable preparation about once every 56 days, and the amount of aripiprazole in the injectable preparation is about 960 mg.

[Claim 14] The method according to claim 13, wherein the injectable preparation further comprises: water, and a suspending agent comprising polyvinylpyrrolidone, polyethylene glycol, and carboxymethylcellulose or a salt thereof, wherein aripiprazole or a salt thereof has a mean primary particle diameter ranging from about 0.5 μm to about 30 μm, and the concentration of aripiprazole in the injectable preparation is about 300 mg/mL.

[Claim 15] The method according to claim 13 or 14, wherein the injectable preparation further comprises: water for injection, and a suspending agent comprising polyvinylpyrrolidone, polyethylene glycol, and carboxymethylcellulose or a salt thereof, wherein the aripiprazole or a salt thereof is aripiprazole monohydrate, the aripiprazole monohydrate has a mean primary particle diameter ranging from about 2 μm to about 5 μm, and the concentration of aripiprazole in the injectable preparation is about 300 mg/mL which is calculated based on the anhydrous form of aripiprazole.

[Claim 16] The method according to any one of claims 13 to 15, wherein an area under the concentration-time curve (AUC) of aripiprazole from time zero to 56 days postdose following a plurality of administration of the injectable preparation is substantially equal to a twofold AUC of aripiprazole from time zero to 28 days postdose following a plurality of administration of an aripiprazole intramuscular (IM) depot formulation such as Abilify Maintena(R) about once every one month (4 weeks or 28 days), e.g., as shown in Figure 2.

[Claim 17] The method of according to any one of claims 13 to 15, further comprising administering aripiprazole in a solid dosage form orally, and the solid dosage form is administered in an amount in a range of 10 mg to 20 mg per day for consecutive 5 to 15 days with the first administration of the injectable preparation.

[Claim 18] The method according to any one of claims 13 to 15, further comprising administering 10 mg to 20 mg of aripiprazole in a solid dosage form orally per day for consecutive 7 days with the first administration of the injectable preparation.

[Claim 19] A method of administering an injectable preparation comprising aripiprazole or a salt thereof to a patient with schizophrenia or bipolar I disorder comprising:
administering orally to the patient 10 to 20 mg/day of aripiprazole or a salt thereof for consecutive 5 to 15 days from a first day;
administering intramuscularly to the patient the injectable preparation once every about 56 days (every about 8 weeks or two months),
wherein the injectable preparation comprising about 650 mg to 1200 mg of aripiprazole is administered on the first day, and a series of the administrations allows the mean plasma level of aripiprazole to maintain 90 ng/mL or more.

[Claim 20] The method according to claim 19, wherein the method does not comprise a further oral administration of aripiprazole or a salt thereof.

[Claim 21] A method of administering a prefilled sol-gel formed injectable preparation comprising aripiprazole or a salt thereof to a patient in need thereof, comprising:
administering 50 to 300 mg of aripiprazole, as a total amount, orally and simultaneously or consecutively from a first day to the 15th day or less; and
administering the prefilled sol-gel formed injectable preparation comprising 650 to 1200 mg of aripiprazole at a gluteal muscle on the

first day; followed by
administering the prefilled sol-gel formed injectable preparation comprising about 650 mg to 1200 mg of aripiprazole at a gluteal muscle once every about 56 days (every about 8 weeks or two months), wherein a series of the administrations allows the mean plasma level of aripiprazole to maintain 90 ng/mL or more.

[Claim 22] The method according to claim 21, wherein the prefilled sol-gel formed injectable preparation is an injectable preparation comprising 300 mg/mL of aripiprazole, having a thixotropic property.

[Claim 23] The method according to claim 21 or 22, wherein the injectable preparation further comprises a suspending agent selected from the group consisting of polyvinylpyrrolidone, polyethylene glycol, carboxymethylcellulose or a salt thereof, and any combination thereof, and the aripiprazole or a salt thereof is aripiprazole monohydrate.

[Claim 24] A method of administering a long acting injectable preparation comprising aripiprazole or a salt thereof to a patient in need thereof, comprising:
administering to the patient the injectable preparation comprising 650 to 1200 mg of aripiprazole at a gluteal muscle once every about 56 days (every about 8 weeks or two months),
wherein the patient has a stable plasma level of aripiprazole by being subject to administration of aripiprazole but is in need of additional administration of aripiprazole, the injectable preparation is in a dosage form of a prefilled sol-gel formed injection, and a series of the administrations allows the mean plasma level of aripiprazole to maintain 90 ng/mL or more.