In one aspect, there is provided use of a non-nucleoside reverse transcriptase inhibitor that is rilpivirine or an equivalent amount of a pharmaceutically acceptable salt of rilpivirine in the manufacture of a medicament for treatment of a pediatric subject, wherein the subject is ≥2 to <12 years infected with an HIV virus, wherein 15 mg or less of the non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine, is to be administered once daily; wherein the subject weighs 11 kg to <25kg; is treatment experienced; and was administered a first anti-retroviral regimen that has been discontinued; or wherein the subject weighs 11 kg to <25kg; and is treatment naïve prior to the administration of the rilpivirine or pharmaceutically acceptable salt of rilpivirine; and wherein the subject exhibits a viral load of less than or equal to 50 copies of HIV virus particles per mL of blood plasma (≤50c/mL) after at least 24 weeks of the once-daily administration of the rilpivirine, or equivalent amount of the pharmaceutically acceptable salt of rilpivirine.

In another aspect, there is provided use of dolutegravir, tenofovir, tenofovir disoproxil fumarate, tenofovir alafenamide, or emtricitabine, or a combination thereof, in the manufacture of a medicament for treatment of a pediatric subject, wherein the subject is ≥2 to <12 years infected with an HIV virus, wherein the dolutegravir, tenofovir, tenofovir disoproxil fumarate, tenofovir alafenamide, or emtricitabine, or a combination thereof; is to be administered to the subject once daily with 15 mg or less of a non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or an equivalent amount of a pharmaceutically acceptable salt of rilpivirine; wherein the subject weighs 11 kg to <25kg; is treatment experienced; and was administered a first anti-retroviral regimen that has been discontinued; or wherein the subject weighs 11 kg to <25kg; and is treatment naïve prior to the administration of the rilpivirine or pharmaceutically acceptable salt of rilpivirine; and wherein the subject exhibits a viral load of less than or equal to 50 copies of HIV virus particles per mL of blood plasma (≤50c/mL) after at least 24 weeks of the once-daily administration of the rilpivirine, or equivalent amount of the pharmaceutically acceptable salt of rilpivirine.

What is claimed:

1. Use of a non-nucleoside reverse transcriptase inhibitor that is rilpivirine or an equivalent amount of a pharmaceutically acceptable salt of rilpivirine in the manufacture of a medicament for treatment of a pediatric subject, wherein the subject is ≥2 to <12 years infected with an HIV virus, wherein

15 mg or less of the non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine, is to be administered once daily;

wherein the subject weighs 11 kg to <25 kg; is treatment experienced; and was administered a first anti-retroviral regimen that has been discontinued; or wherein the subject weighs 11 kg to <25kg; and is treatment naïve prior to the administration of the rilpivirine or pharmaceutically acceptable salt of rilpivirine;

and

wherein the subject exhibits a viral load of less than or equal to 50 copies of HIV virus particles per mL of blood plasma (≤50c/mL) after at least 24 weeks of the once-daily administration of the rilpivirine, or equivalent amount of the pharmaceutically acceptable salt of rilpivirine.

2. The use of claim 1, wherein the subject is to be administered a pharmaceutically acceptable salt of rilpivirine.

3. The use of claim 1 or claim 2, wherein the pharmaceutically acceptable salt of rilpivirine is the hydrochloride salt of rilpivirine.

4. The use of any one of the preceding claims, wherein the pediatric subject is to be further administered dolutegravir, tenofovir, tenofovir disoproxil fumarate, tenofovir alafenamide, emtricitabine, or a combination thereof.

5. The use of any one of the preceding claims, wherein the pediatric subject is treatment experienced.

6. The use of a claim 5, wherein the pediatric subject exhibits a viral load of less than or equal to 50 copies of HIV virus particles per mL of blood plasma (≤50c/mL) prior to

the once-daily administration of the rilpivirine, or equivalent amount of the pharmaceutically acceptable salt of rilpivirine.

7. The use of any one of claims 1 to 4, wherein the pediatric subject is treatment naïve prior to the administration of the rilpivirine or the pharmaceutically acceptable salt of rilpivirine.

8. The use of any one of the preceding claims, wherein the HIV virus is HIV-1.

9. The use of any one of the preceding claims, wherein the 15 mg or less of the non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine, is to be administered as a single unit dosage form.

10. The use of any one of claims 1 to 8, wherein the 15 mg or less of the non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine, is to be administered in multiple single unit dosage forms.

11. The use of claim 10, wherein the daily dose is 15 mg of rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine, and said 15 mg is to be administered as six tablets or capsules, each tablet or capsule containing 2.5 mg of rilpivirine.

12. The use of any one of the preceding claims, wherein the subject exhibits a viral load of less than or equal to 50 copies of HIV-1 virus particles per mL of blood plasma (≤ 50c/mL) after at least 48 weeks of once daily administration of the rilpivirine, or the pharmaceutically acceptable salt of rilpivirine.

13. The use of any one of claims 1 to 10, wherein 15 mg of rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine is to be administered.

14. The use of dolutegravir, tenofovir, tenofovir disoproxil fumarate, tenofovir alafenamide, or emtricitabine, or a combination thereof, in the manufacture of a medicament for treatment of a pediatric subject, wherein the subject is ≥2 to <12 years infected with an HIV virus, wherein

the dolutegravir, tenofovir, tenofovir disoproxil fumarate, tenofovir alafenamide, or emtricitabine, or a combination thereof;

is to be administered to the subject once daily with

15 mg or less of a non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or an equivalent amount of a pharmaceutically acceptable salt of rilpivirine;

wherein the subject weighs 11 kg to <25kg; is treatment experienced; and was administered a first anti-retroviral regimen that has been discontinued; or wherein the subject weighs 11 kg to <25kg; and is treatment naïve prior to the administration of the rilpivirine or pharmaceutically acceptable salt of rilpivirine; and

wherein the subject exhibits a viral load of less than or equal to 50 copies of HIV virus particles per mL of blood plasma (≤50c/mL) after at least 24 weeks of the once-daily administration of the rilpivirine, or equivalent amount of the pharmaceutically acceptable salt of rilpivirine.

15. The use of claim 14, wherein:

- the subject is to be administered a pharmaceutically acceptable salt of rilpivirine;
- the pharmaceutically acceptable salt of rilpivirine is the hydrochloride salt of rilpivirine;
- the pediatric subject is treatment experienced;
- the pediatric subject exhibits a viral load of less than or equal to 50 copies of HIV virus particles per mL of blood plasma (≤50c/mL) prior to the once-daily administration of the rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine;
- the pediatric subject is treatment naïve prior to the administration of the rilpivirine or pharmaceutically acceptable salt of rilpivirine;
- the HIV virus is HIV-1;
- the 15 mg or less of the non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine, is to be administered as a single unit dosage form;
- the 15 mg or less of the non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine, is to be administered in multiple single unit dosage forms;

- the daily dose is 15 mg of rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine, and said 15 mg is to be administered as six tablets or capsules, each tablet or capsule containing 2.5 mg of rilpivirine;
- the daily dose is 15 mg of rilpivirine, or the equivalent amount of the pharmaceutically acceptable salt of rilpivirine; and/or
- the subject exhibits a viral load of less than or equal to 50 copies of HIV-1 virus particles per mL of blood plasma (≤ 50c/mL) after at least 48 weeks of once daily administration of the rilpivirine, or the pharmaceutically acceptable salt of rilpivirine.