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 infected with an HIV virus, wherein 25 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 or more; is treatment experienced; and was administered a first anti-retroviral regimen that has been discontinued; or wherein the subject weighs 11 kg or more; 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, emtricitabine, or a combination thereof, in the manufacture of a medicament for treatment of a pediatric subject infected with an HIV virus, wherein the dolutegravir, tenofovir, tenofovir disoproxil fumarate, tenofovir alafenamide, emtricitabine, or a combination thereof; and 25 mg or less of a non-nucleoside reverse transcriptase inhibitor that is rilpivirine, or an equivalent amount of a pharmaceutically acceptable salt of rilpivirine, is to be administered to the subject once daily; wherein the subject weighs 11 kg or more; is treatment experienced; and was administered a first anti-retroviral regimen that has been discontinued; or wherein the subject weighs 11 kg or more; 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 method of treating~~ a pediatric subject infected with an HIV virus ~~comprising administering to the subject~~, wherein~~:~~

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

   wherein the subject weighs 11 kg or more; is treatment experienced; and was administered a first anti-retroviral regimen that has been discontinued; or wherein the subject weighs 11 kg or more; 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 ~~method~~ use of claim 1, wherein the subject is to be administered a pharmaceutically acceptable salt of rilpivirine.

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

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

5. The ~~method~~ use of any one of the preceding claims, wherein the pediatric subject is ≥2 to <12 years.

6. The use ~~method~~ of any one of the preceding claims, wherein the pediatric subject has a body weight of <25 kg.

7. The use of any one of the preceding claims, wherein less than 25 mg 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.

~~7.~~8. The use ~~method~~ of any one of the preceding claims, wherein the pediatric subject has a body weight of ≤70 kg

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

~~8.~~10. The use ~~method~~ of a~~ny one of the preceding~~ claim~~s~~ 9, 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.

11. The use of any one of claims 1 to 8, wherein the pediatric subject is treatment naïve prior to the administration of the rilpivirine or the pharmaceutically acceptable salt of rilpivirine.

~~9.~~12. The use ~~method~~ of any one of the preceding claims, wherein the HIV virus is HIV-1.

~~10.~~13. The use ~~method~~ of any one of the preceding claims, wherein the 25 mg or less of ~~a~~ 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.

~~11.~~14. The use ~~method~~ of any one of claims 1 to ~~8~~12, wherein the 25 mg or less of ~~a~~ 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.

15. The use of claim 14, 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.~~16. The ~~method~~ 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.

17. The use of dolutegravir, tenofovir, tenofovir disoproxil fumarate, tenofovir alafenamide, emtricitabine, or a combination thereof, in the manufacture of a medicament for treatment of a pediatric subject infected with an HIV virus, wherein the dolutegravir, tenofovir, tenofovir disoproxil fumarate, tenofovir alafenamide, emtricitabine, or a combination thereof;

and

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

wherein the subject weighs 11 kg or more; is treatment experienced; and was administered a first anti-retroviral regimen that has been discontinued; or wherein the subject weighs 11 kg or more; 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.

18. The use of claim 17, 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 ≥2 to <12 years;

- less than 25 mg 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;
- the pediatric subject has a body weight of ≤70 kg;
- 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 25 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 25 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; 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.