[0012] In another embodiment, the present disclosure is related to one or more of the foregoing methods, wherein the method comprises administering a pharmaceutically acceptable salt of atrasentan, and in particular comprises administering atrasentan HCl.

[0012a] In another embodiment, the present disclosure relates to the use of atrasentan, or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for reducing cardiovascular risk in a subject, wherein the medicament is to be administered in an amount sufficient to effect a reduction of about 5% or more in one or both of (a) total serum cholesterol, relative to a baseline total serum cholesterol of the subject, and (b) serum LDL cholesterol, relative to a baseline serum LDL cholesterol of the subject.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 is a graph illustrating Geometric Mean Change from Baseline in UACR over a 12 week period, as further discussed in Example 1.

[0014] Figure 2 is a graph illustrating Least Squares (LS) Mean Changes in eGFR from Baseline over time, as further discussed in Example 1.

[0015] Figure 3 is a graph illustrating Mean Systolic Blood Pressure Changes from Baseline over time, as further discussed in Example 1.

[0016] Figure 4 is a graph illustrating Mean Diastolic Blood Pressure Changes from Baseline over time, as further discussed in Example 1.

[0017] Figure 5 is a flow chart illustrating Path Analysis for Evaluating Treatment Effect on Change in UACR, after accounting for the treatment effect on change in systolic blood pressure, as further discussed in Example 1.

[0018] Figure 6 is a graph illustrating the Mean (Ambulatory) Systolic Blood Pressure Changes from Baseline over time (24 hours), as further discussed in Example 1.

[0019] Figure 7 is a graph illustrating the Mean (Ambulatory) Diastolic Blood Pressure Changes from Baseline over time (24 hours), as further discussed in Example 1.

[0020] Figure 8 is a graph illustrating Mean Weight Change from Baseline over time, as further discussed in Example 1.

[0021] Figure 9 is a graph illustrating Geometric Mean Change from Baseline in UACR over a 12 week period, as further discussed in Example 2.

[0022] Figure 10 is a graph illustrating Least Squares (LS) Mean Changes in eGFR from Baseline over time, as further discussed in Example 2.

[0023] Figure 11 is a graph illustrating Mean Systolic Blood Pressure Changes from Baseline over time, as further discussed in Example 2.

[0024] Figure 12 is a graph illustrating Mean Diastolic Blood Pressure Changes from Baseline over time, as further discussed in Example 2.

WHAT IS CLAIMED IS:

1. Use of atrasentan, or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for~~A method of~~ reducing cardiovascular risk in a ~~human~~ subject, ~~the method comprising administering atrasentan, or a pharmaceutically acceptable salt thereof,~~ wherein the medicament is to be administered in an amount sufficient to effect a reduction of about 5% or more in one or both of (a) total serum cholesterol, relative to a baseline total serum cholesterol of the subject, and (b) serum LDL cholesterol, relative to a baseline serum LDL cholesterol of the subject.

2. The ~~method~~ use of claim 1, wherein a reduction is effected for both (a) total serum cholesterol, relative to a baseline total serum cholesterol of the subject, and (b) serum LDL cholesterol, relative to a baseline serum LDL cholesterol of the subject.

3. The ~~method~~ use of any one of the preceding claims, wherein the atrasentan is a pharmaceutically acceptable salt thereof~~of atrasentan is administered to the subject~~.

4. The ~~method~~ use of claim 3, wherein the pharmaceutically acceptable salt ~~administered to the subject~~ is atrasentan hydrochloride.

~~5. The method of one of the preceding claims, wherein total serum cholesterol is reduced by about 10% or more, relative to the subject's baseline total serum cholesterol.~~

~~6. The method of claim 5, wherein the total serum cholesterol is reduced by about 15% or more, relative to the subject's baseline total serum cholesterol.~~

~~7. The method of claim 6, wherein the total serum cholesterol is reduced by about 20% or more, relative to the subject's baseline total serum cholesterol.~~

~~8~~5. The ~~method~~ use of claim 1, wherein the total serum cholesterol is reduced by about 10% to about 25%, relative to the ~~subject's~~ baseline total serum cholesterol.

~~9~~6. The ~~method~~ use of claim ~~8~~5, wherein the total serum cholesterol is reduced by about 15% to about 25%, relative to the ~~subject's~~ baseline total serum cholesterol.

~~10. The method of one of the preceding claims, wherein serum LDL cholesterol is reduced by about 10% or more, relative to the subject's baseline serum LDL cholesterol.~~

~~11. The method of claim 10, wherein the serum LDL cholesterol is reduced by about 15% or more, relative to the subject's baseline serum LDL cholesterol.~~

~~12. The method of claim 11, wherein the serum LDL cholesterol is reduced by about 20% or more, relative to the subject's baseline serum LDL cholesterol.~~

~~13~~7. The ~~method~~ use of ~~claim 10~~ any one of the preceding claims, wherein the serum LDL cholesterol is reduced by about 10% to about 25%, relative to the ~~subject's~~ baseline serum LDL cholesterol.

~~14~~8. The ~~method~~ use of claim ~~13~~7, wherein the serum LDL cholesterol is reduced by about 15% to about 25%, relative to the ~~subject's~~ baseline serum LDL cholesterol.

~~15. The method of any claim one of the preceding claims, wherein total serum cholesterol is reduced, relative to baseline, by about 10 mg/dL or more.~~

~~16~~9. The ~~method~~ use of ~~claim 15~~ any one of the preceding claims, wherein total serum cholesterol is reduced, relative to baseline, by about 20 mg/dL or more.

~~17~~10. The ~~method~~ use of ~~claim 15~~ any one of claims 1 to 8, wherein total serum cholesterol is reduced, relative to baseline, by about 10 mg/dL to about 25 mg/dL.

~~18. The method of claim 17, wherein total serum cholesterol is reduced, relative to baseline, by about 15 mg/dL to about 25 mg/dL.~~

~~19~~11. The ~~method~~ use of ~~claim~~ any one of the preceding claims, wherein serum LDL cholesterol is reduced, relative to baseline, by about 10 mg/dL or more.

~~20. The method of claim 19, wherein serum LDL cholesterol is reduced, relative to baseline, by about 20 mg/dL or more.~~

~~21~~12. The ~~method~~ use of claim ~~19~~ 11, wherein serum LDL cholesterol is reduced, relative to baseline, by about 10 mg/dL to about 25 mg/dL.

~~22~~13. The ~~method~~ use of claim ~~21~~ 12, wherein serum LDL cholesterol is reduced, relative to baseline, by about 15 mg/dL to about 25 mg/dL.

~~23. The method of one of the preceding claims, wherein about 0.25 mg to about 250 mg atrasentan, or a pharmaceutically acceptable salt thereof, is administered to the subject.~~

~~24. The method of claim 23, wherein about 0.5 mg to about 200 mg atrasentan, or a pharmaceutically acceptable salt thereof, is administered to the subject.~~

~~25. The method of claim 24, wherein about 0.5 mg to about 100 mg atrasentan, or a pharmaceutically acceptable salt thereof, is administered to the subject.~~

~~26. The method of claim 25, wherein about 0.5 mg to about 50 mg atrasentan, or a pharmaceutically acceptable salt thereof, is administered to the subject.~~

~~27. The method of claim 26, wherein about 0.5 mg to about 25 mg atrasentan, or a pharmaceutically acceptable salt thereof, is administered to the subject.~~

~~28~~14. The ~~method~~ use of ~~claim 27~~ any one of the preceding claims, wherein about 0.5 mg to about 10 mg atrasentan, or a pharmaceutically acceptable salt thereof, is to be administered to the subject.

~~29~~15. The ~~method~~ use of claim ~~28~~ 14, wherein about 0.5 mg to about 1.5 mg atrasentan, or a pharmaceutically acceptable salt thereof, is to be administered to the subject.

~~30~~16. The ~~method~~ use of claim ~~29~~ 15, wherein about 0.75 mg to about 1.25 mg atrasentan, or a pharmaceutically acceptable salt thereof, is to be administered to the subject.

~~31~~17. The ~~method~~ use of claim ~~30~~ 16, wherein about 0.75 mg atrasentan, or a pharmaceutically acceptable salt thereof, is to be administered to the subject.

~~32~~18. The ~~method~~ use of any one of the preceding claims, wherein atrasentan, or a pharmaceutically acceptable salt thereof, is to be administered daily to the subject.

~~33~~19. The ~~method~~ use of any one of the preceding claims, further comprising the use of a HMG-CoA reductase inhibitor in the manufacture of a pharmaceutical composition wherein the pharmaceutical composition is to be administered ~~administering a therapeutically effective amount of a HMG-CoA reductase inhibitor~~ to the subject.

~~34~~20. The ~~method~~ use of claim ~~33~~19, further comprising the use of a statin in the manufacture of a pharmaceutical composition wherein the pharmaceutical composition is to be administered ~~administering a therapeutically effective amount of a statin~~ to the subject.

~~35~~21. The ~~method~~ use of any one of the preceding claims, wherein the subject is susceptible to or suffering from an illness selected from the group consisting of coronary heart disease, hypercholesterolemia, hyperlipidemia, nephropathy, chronic kidney disease, diabetes, and albuminuria.

~~36~~22. The ~~method~~ use of claim ~~35~~21, wherein the subject is susceptible to or suffering from hypercholesterolemia.

~~37~~23. The ~~method~~ use of claim ~~35~~21, wherein the subject is susceptible to or suffering from hyperlipidemia.

~~38~~24. The ~~method~~ use of claim ~~35~~21, wherein the subject is susceptible to or suffering from diabetes.

~~39~~25. The ~~method~~ use of claim ~~38~~24, wherein the subject is suffering from type 2 diabetes.