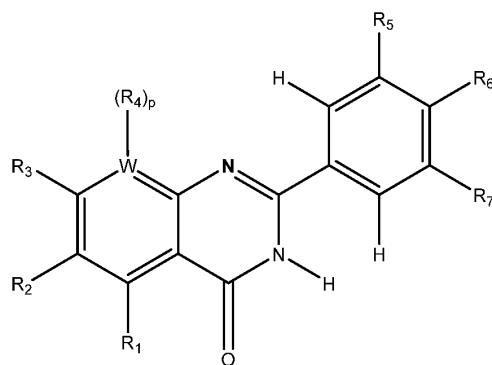


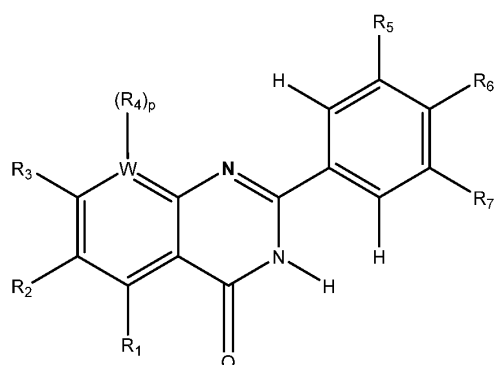
### Claims

1. A method for treating and/or preventing major adverse cardiovascular events (MACE) comprising administering to a subject in need thereof, a sodium-glucose transport protein 2 (SGLT2) inhibitor and a compound of Formula I or a stereoisomer, tautomer, pharmaceutically acceptable salt, or hydrate thereof, wherein:



Formula I

- R<sub>1</sub> and R<sub>3</sub> are each independently selected from alkoxy, alkyl, amino, halogen, and hydrogen;
- R<sub>2</sub> is selected from alkoxy, alkyl, alkenyl, alkynyl, amide, amino, halogen, and hydrogen;
- R<sub>5</sub> and R<sub>7</sub> are each independently selected from alkyl, alkoxy, amino, halogen, and hydrogen;
- R<sub>6</sub> is selected from amino, amide, alkyl, hydrogen, hydroxyl, piperazinyl, and alkoxy;
- W is selected from C and N, wherein if W is N, then p is 0 or 1, and if W is C, then p is 1; and for W-(R<sub>4</sub>)<sub>p</sub>, W is C, p is 1 and R<sub>4</sub> is H, or W is N and p is 0.
2. A method for treating and/or preventing any individual component of MACE comprising administering to a subject in need thereof, a sodium-glucose transport protein 2 (SGLT2) inhibitor and a compound of Formula I or a stereoisomer, tautomer, pharmaceutically acceptable salt, or hydrate thereof, wherein:



Formula I

R<sub>1</sub> and R<sub>3</sub> are each independently selected from alkoxy, alkyl, amino, halogen, and hydrogen;

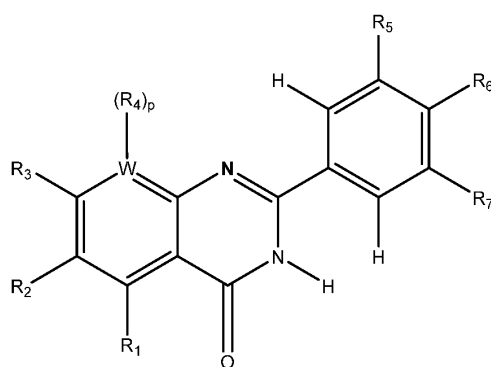
R<sub>2</sub> is selected from alkoxy, alkyl, alkenyl, alkynyl, amide, amino, halogen, and hydrogen;

R<sub>5</sub> and R<sub>7</sub> are each independently selected from alkyl, alkoxy, amino, halogen, and hydrogen;

R<sub>6</sub> is selected from amino, amide, alkyl, hydrogen, hydroxyl, piperazinyl, and alkoxy;

W is selected from C and N, wherein if W is N, then p is 0 or 1, and if W is C, then p is 1; and for W-(R<sub>4</sub>)<sub>p</sub>, W is C, p is 1 and R<sub>4</sub> is H, or W is N and p is 0.

3. The method of claim 1 or claim 2, wherein the compound of Formula I is selected from compounds of Formula 1a:



Formula 1a

or a stereoisomer, tautomer, pharmaceutically acceptable salt, or hydrate thereof, wherein:

R<sub>1</sub> and R<sub>3</sub> are each independently selected from alkoxy, alkyl, and hydrogen;

R<sub>2</sub> is selected from alkoxy, alkyl, and hydrogen;

R<sub>5</sub> and R<sub>7</sub> are each independently selected from alkyl, alkoxy, and hydrogen;

R<sub>6</sub> is selected from alkyl, hydroxyl, and alkoxy;

W is selected from C and N, wherein if W is N, then p is 0 or 1, and if W is C, then p is 1;

and

for W-(R<sub>4</sub>)<sub>p</sub>, W is C, p is 1 and R<sub>4</sub> is H, or W is N and p is 0.

4. The method of any one of claims 1 to 3, wherein the compound of Formula I or Ia is 2-(4-(2-hydroxyethoxy)-3,5-dimethylphenyl)-5,7-dimethoxyquinazolin-4(3H)-one (RVX-208 or RVX000222) or a pharmaceutically acceptable salt thereof.
5. The method according to any one claim of claims 1 to 4, comprising administering a daily dose of 200 mg of 2-(4-(2-hydroxyethoxy)-3,5-dimethylphenyl)-5,7-dimethoxyquinazolin-4(3H)-one or an equivalent amount of a pharmaceutically acceptable salt thereof to a subject in need thereof.
6. The method of claim 5, wherein a subject in need thereof is administered 100 mg of 2-(4-(2-hydroxyethoxy)-3,5-dimethylphenyl)-5,7-dimethoxyquinazolin-4(3H)-one or an equivalent amount of a pharmaceutically acceptable salt thereof twice daily.
7. The method according to any one claim of claims 1 to 6, wherein the SGLT2 inhibitor is selected from empagliflozin, canagliflozin, remogliflozin, ipragliflozin, HM41322, and dapagliflozin.
8. The method according to any one claim of claims 1 to 6, wherein the SGLT2 inhibitor is selected from bexagliflozin, ertugliflozin, sotagliflozin, luseogliflozin, and tofogliflozin.
9. The method according to any one claim of claims 1 to 8, wherein the subject is a human.
10. The method according to any one claim of claims 1 to 9, wherein the subject is a human with type 2 diabetes and low HDL cholesterol (below 40mg/dL for males and below 45 mg/dL for females) and a recent acute coronary syndrome (ACS) (preceding 7-90 days).
11. The method according to any one claim of claims 1-10, wherein the subject is on statin therapy.

12. The method according to any one of claims 1-11, wherein the MACE is selected from non-fatal myocardial infarction, cardiovascular death, stroke, and hospitalization for cardiovascular disease events.
13. The method according to claim 12, wherein the cardiovascular disease event is congestive heart failure.
14. The method according to claim 12, wherein the hospitalization for cardiovascular disease events is hospitalization for congestive heart failure.
15. The method according to any one of claims 1-11, wherein the MACE is selected from non-fatal myocardial infarction, cardiovascular death, and stroke.