WHAT IS CLAIMED IS:

1. A method for a condition in a mammal characterized by undesired thrombosis comprising administering to said mammal a therapeutically effective amount of the following therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) a therapeutic agent selected from the group consisting of an anticoagulant agent, an antiplatelet agent, and combinations thereof.

2. The method of claim 1 comprising administering to said mammal a therapeutically effective amount of the following two therapeutic agents:

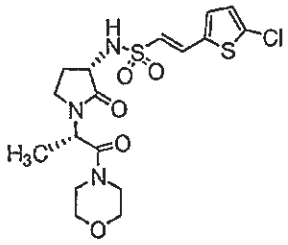
(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

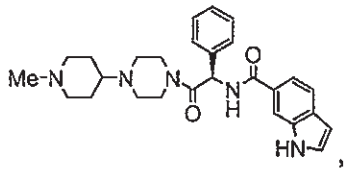
(2) an anticoagulant agent.

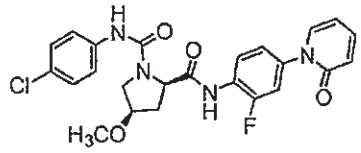
3. The method according to claim 2, wherein the anticoagulant agent is a factor Xa inhibitor.

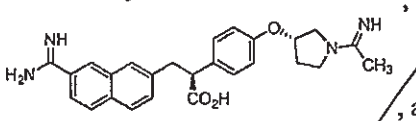
4. The method according to claim 3, wherein the factor Xa inhibitor is selected from the group consisting of YM-150, Daiichi DU-176b, *N*-{(1R)-2-[4-(1-methyl-4-piperidinyl)-1-piperazinyl]-2-oxo-1-phenylethyl}-1*H*-indole-6-carboxamide, apixaban, rivaroxaban, otamixaban, and razaxaban.

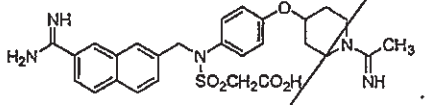
5. The method according to claim 3, wherein the factor Xa inhibitor is selected from the group consisting of:




,


,


, and


.

6. The method according to claim 3, wherein the factor Xa inhibitor is betrixaban, or a pharmaceutically acceptable salt thereof.

7. The method according to claim 6, wherein the pharmaceutically acceptable salt of betrixaban is the maleate salt.

8. The method according to claim 2, wherein the anticoagulant agent is selected from the group consisting of specific inhibitors of thrombin, factor IXa, factor XI, factor XIa or factor VIIa.

9. The method according to claim 2, wherein the anticoagulant agent is selected from the group consisting of AZD0837, RB2006, ximelagatran, dabigatran, bivalirudin, argatroban, lepirudin, warfarin, and phenocoumarol.

10. The method according to claim 2, wherein the anticoagulant agent is an injectable anticoagulant agent.

11. The method according to claim 2, wherein the anticoagulant agent is selected from the group consisting of synthetic pentasaccharides and low molecular weight heparin.

12. The method according to claim 2, wherein the anticoagulant agent is selected from the group consisting of fondaparinux, idraparinux, biotinylated idraparinux, danaparoid, enoxaparin, dalteparin and unfractionated heparin.

13. The method according to claim 2, wherein the anticoagulant agent is an anti-factor XI antibody.

14. The method according to claim 2, wherein the anticoagulant agent is bivalirudin.

15. The method of claim 1 comprising administering to said mammal a therapeutically effective amount of the following two therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) another antiplatelet agent.

16. The method according to claim 15, wherein the antiplatelet agent is an antagonist of TP receptor or a cyclooxygenase inhibitor.

17. The method according to claim 16, wherein the cyclooxygenase inhibitor is a reversible cyclooxygenase-1 inhibitor.

18. The method according to claim 15, wherein the antiplatelet agent is selected from the group consisting of acetylsalicylic acid, abciximab, eptifibatide, tirofiban, dipyridamole, aggrenox, cilostazol, ifetroban, isbogrel, furegrelate, resveratrol and ozagrel.

19. The method according to any one of claims 1-18, wherein at least one of the therapeutic agents is administered in a sub-therapeutic dosage.

20. The method according to any one of claims 1-18, wherein both of the therapeutic agents are administered in sub-therapeutic dosages.

21. The method according to any one of claims 1-18, wherein the two therapeutic agents are administered simultaneously.

22. The method according to any one of claims 1-18, wherein the two therapeutic agents are administered sequentially.

23. The method of claim 1, comprising administering to said mammal a therapeutically effective amount of the following three therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof;

(2) an antiplatelet agent; and

(3) an anticoagulant agent.

24. The method according to claim 23, wherein the antiplatelet agent is a cyclooxygenase inhibitor.

25. The method according to claim 23, wherein the antiplatelet agent is acetylsalicylic acid.

26. The method according to claim 23, wherein the anticoagulant agent is a factor Xa inhibitor.

27. The method according to claim 26, wherein the factor Xa inhibitor is betrixaban, or a pharmaceutically acceptable salt thereof.

28. The method according to claim 27, wherein the pharmaceutically acceptable salt of betrixaban is the maleate salt.

29. The method according to any one of claims 23-28, wherein at least one of the therapeutic agents is administered in a sub-therapeutic dosage.

30. The method according to any one of claims 23-28, wherein all of the therapeutic agents are administered in sub-therapeutic dosages.

31. The method according to any one of claims 23-28, wherein the three therapeutic agents are administered simultaneously.

32. The method according to any one of claims 23-28, wherein the three therapeutic agents are administered sequentially.

33. The method according to any one of claims 1-18 and 23-28, wherein the pharmaceutically acceptable salt of [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-

quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea is the potassium salt or sodium salt.

34. The method according to any one of claims 1-18 and 23-28, wherein said thrombosis-related condition is selected from the group consisting of acute myocardial infarction, unstable angina, chronic stable angina, transient ischemic attacks, strokes, peripheral vascular disease, preeclampsia/eclampsia, deep venous thrombosis, embolism, disseminated intravascular coagulation and thrombotic cytopenic purpura, thrombotic and restenotic complications following invasive procedures resulting from angioplasty, carotid endarterectomy, post CABG (Coronary arteryl bypass graft) surgery, vascular graft surgery, stent placements and insertion of endovascular devices and prosthesis.

35. A pharmaceutical composition, comprising a pharmaceutically acceptable carrier and the following therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) a therapeutic agent selected from the group consisting of an anticoagulant agent, an antiplatelet agent and combinations thereof.

36. The pharmaceutical composition of claim 35, comprising a pharmaceutically acceptable carrier and the following two therapeutic agents:

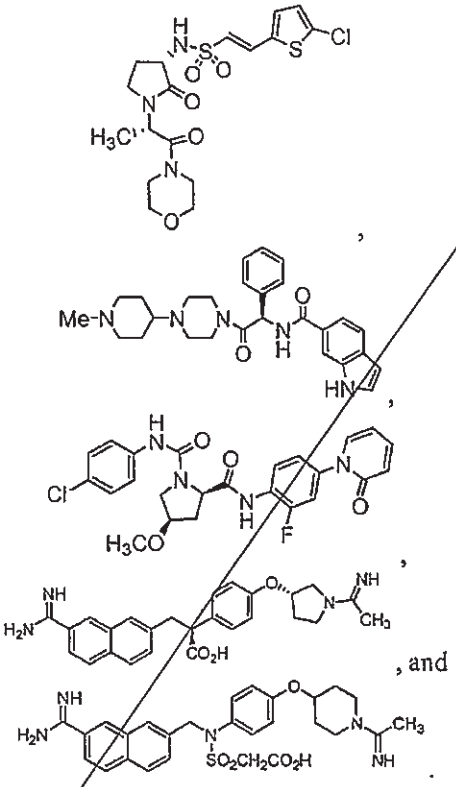
(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) an anticoagulant agent.

37. The pharmaceutical composition according to claim 36, wherein the anticoagulant agent is a factor Xa inhibitor.

38. The pharmaceutical composition according to claim 37, wherein the factor Xa inhibitor is selected from the group consisting of YM-150, Daiichi DU-176b, *N*-{(1R)-2-[4-(1-methyl-4-piperidinyl)-1-piperazinyl]-2-oxo-1-phenylethyl}-1*H*-indole-6-

carboxamide, apixaban, rivaroxaban, otamixaban, and razaxaban or is selected from the group consisting of:



39. The pharmaceutical composition according to claim 37, wherein the factor Xa inhibitor is betrixaban, or a pharmaceutically acceptable salt thereof.

40. The pharmaceutical composition according to claim 39, wherein the pharmaceutically acceptable salt of betrixaban is the maleate salt.

41. The pharmaceutical composition according to claim 37, wherein the anticoagulant is selected from the group consisting of specific inhibitors of thrombin, factor IXa, factor XI, factor XIa or factor VIIa.

42. The pharmaceutical composition according to claim 37, wherein the anticoagulant agent is selected from the group consisting of AZD0837, RB2006, ximelagatran, dabigatran, bivalirudin, argatroban, lepirudin, warfarin, and phenocoumarol.

43. The pharmaceutical composition according to claim 37, wherein the anticoagulant agent is an injectable anticoagulant agent.

44. The pharmaceutical composition according to claim 37, wherein the anticoagulant is selected from the group consisting of synthetic pentasaccharides and low molecular weight heparin.

45. The pharmaceutical composition according to claim 37, wherein the anticoagulant is selected from the group consisting of fondaparinux, idraparinux, biotinylated idraparinux, danaparoid, enoxaparin, dalteparin and unfractionated heparin.

46. The pharmaceutical composition according to claim 37, wherein the anticoagulant agent is an anti-factor XI antibody.

47. The pharmaceutical composition of claim 35 comprising a pharmaceutically acceptable carrier and the following two therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) another antiplatelet agent.

48. The pharmaceutical composition according to claim 47, wherein the antiplatelet agent is an antagonist of TP receptor or a cyclooxygenase inhibitor.

49. The pharmaceutical composition according to claim 48, wherein the cyclooxygenase inhibitor is a reversible cyclooxygenase-1 inhibitor.

50. The pharmaceutical composition according to claim 47, wherein the antiplatelet agent is selected from the group consisting of abciximab, acetylsalicylic acid, eptifibatide, tirofiban, dipyridamole, aggrenox, cilostazol, isbogrel, ifetroban, resveratrol, furegrelate and ozagrel.

51. The pharmaceutical composition according to any one of claims 35-50, wherein at least one of the two therapeutic agents is present in a sub-therapeutic dosage.

52. The pharmaceutical composition according to any one of claims 35-50, wherein both of the two therapeutic agents are present in sub-therapeutic dosages.

53. The pharmaceutical composition of claim 35 comprising a pharmaceutically acceptable carrier and the following three therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof;

(2) another antiplatelet agent; and

(3) an anticoagulant agent.

54. The pharmaceutical composition according to claim 53, wherein the antiplatelet agent is a cyclooxygenase inhibitor.

55. The pharmaceutical composition according to claim 53, wherein the antiplatelet agent is acetylsalicylic acid.

56. The pharmaceutical composition according to claim 53, wherein the anticoagulant agent is a factor Xa inhibitor.

57. The pharmaceutical composition according to claim 56, wherein the factor Xa inhibitor is betrixaban, or a pharmaceutically acceptable salt thereof.

58. The pharmaceutical composition according to claim 57, wherein the pharmaceutically acceptable salt of betrixaban is the maleate salt.

59. The method according to any one of claims 53-57, wherein at least one of the therapeutic agents is administered in a sub-therapeutic dosage.

60. The method according to any one of claims 53-57, wherein all of the therapeutic agents are administered in sub-therapeutic dosages.

61. The pharmaceutical composition according to any one of claims 35-50 and 53-57, wherein the pharmaceutically acceptable salt of [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea is the potassium salt or the sodium salt.

62. A kit comprising:

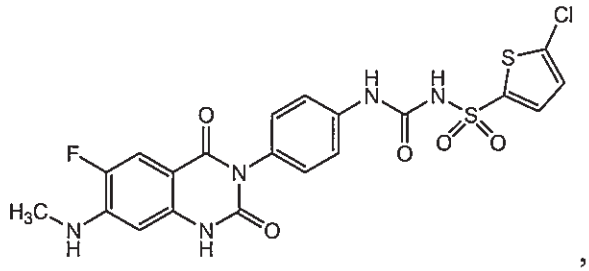
(1) a first container, wherein said first container contains [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) a second container, wherein said second container contains an anticoagulant agent or another antiplatelet agent.

63. The kit according to claim 62, further comprising a package insert stating that the two therapeutic agents can be used together.

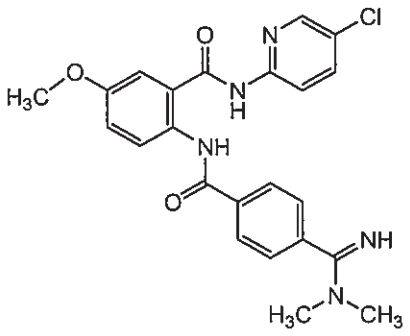
CLAIMS

1. A compound which is [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, of the formula

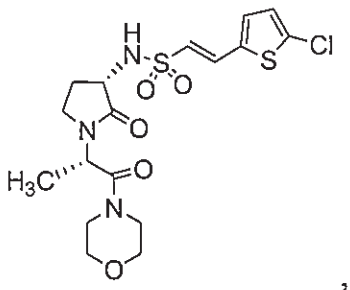


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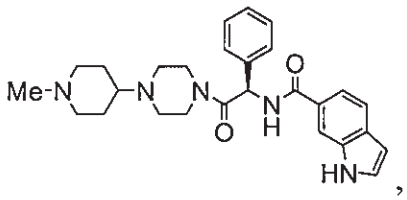
or a pharmaceutically acceptable salt thereof, for use in the treatment of a condition in a mammal characterized by undesired thrombosis, said compound is to be administered in combination with a therapeutic agent selected from the group consisting of specific inhibitors of thrombin, specific inhibitors of factor IXa, specific inhibitors of factor XI, specific inhibitors of factor XIa, specific inhibitors of factor VIIa, lepirudin, phenocoumarol, synthetic pentasaccharides, dipyridamole, aggrenox, cilostazol, ifetroban, isbogrel, furegrelate, resveratrol, ozagrel, an anti-factor XI antibody, YM-150, Daiichi DU-176b, N-{(1R)-2-[4-(1-methyl-4-piperidinyl)-1-piperazinyl]-2-oxo-1-phenylethyl}-1H-indole-6-carboxamide, apixaban, rivaroxaban, otamixaban, razaxaban,



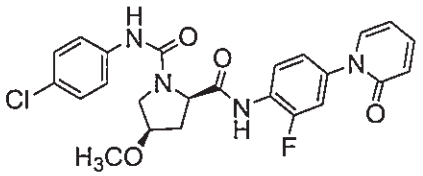
Betrixaban,



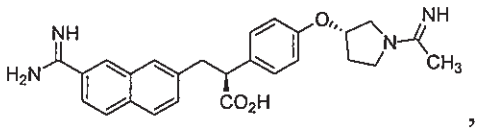
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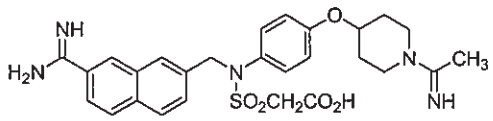
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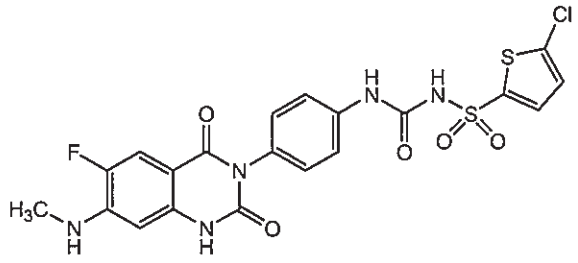
, and



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and combinations thereof.

2. A compound which is [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, which is of the formula



,

or a pharmaceutically acceptable salt thereof for use in the treatment of a condition in a mammal characterized by undesired thrombosis,

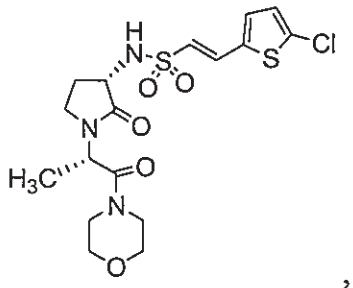
said compound is to be administered in combination with a therapeutic agent selected from the group consisting of an anticoagulant agent, an antiplatelet agent, and combinations thereof,

wherein at least one of the compound and the therapeutic agent is used in a

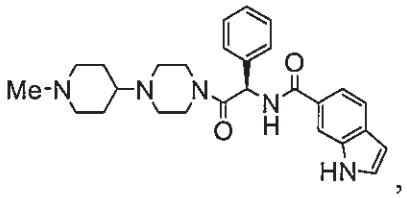
sub-therapeutic dosage.

3. The compound according to claim 2, wherein the anticoagulant agent is a factor Xa inhibitor.

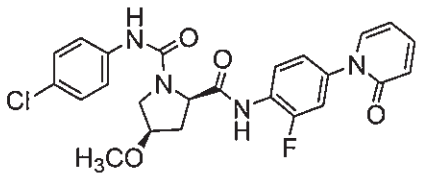
4. The compound according to claim 1 or 2, wherein the therapeutic agent is selected from the group consisting of YM-150, Daiichi DU-176b, *N*-{(1R)-2-[4-(1-methyl-4-piperidinyl)-1-piperazinyl]-2-oxo-1-phenylethyl}-1*H*-indole-6-carboxamide, apixaban, rivaroxaban, otamixaban, and razaxaban,



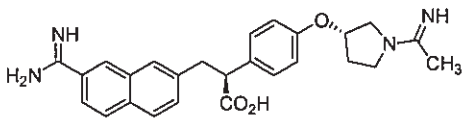
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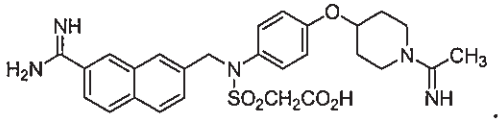
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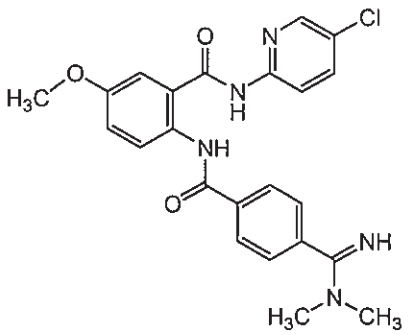


, and



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5. The compound according to claim 1 or 2, wherein the therapeutic agent is betrixaban



or a pharmaceutically acceptable salt thereof, optionally wherein the pharmaceutically acceptable salt of betrixaban is the maleate salt.

6. The compound of claim 1 or 2 wherein the therapeutic agent is selected from the group consisting of, dipyridamole, aggrenox, cilostazol, ifetroban, isbogrel, furegrelate, resveratrol, and ozagrel.

7. The compound according to claim 1 or 2, wherein the therapeutic agent is:

(i) selected from the group consisting of specific inhibitors of thrombin, factor IXa, factor XI, factor XIa or factor VIIa;

(ii) selected from the group consisting of AZD0837, RB2006, ximelagatran, dabigatran, bivalirudin, argatroban, lepirudin, and phenocoumarol;

(iii) selected from the group consisting of synthetic pentasaccharides;

(iv) selected from the group consisting of fondaparinux, idraparinux, biotinylated idraparinux, danaparoid, enoxaparin, and dalteparin ;

(v) an anti-factor XI antibody; or

(vi) bivalirudin.

8. The compound according to claim 2, wherein the therapeutic agent is:

(i) an antagonist of TP receptor or a cyclooxygenase inhibitor, optionally wherein the cyclooxygenase inhibitor is a reversible cyclooxygenase-1 inhibitor; or

(ii) selected from the group consisting of acetylsalicylic acid, unfractionated heparin, , dipyridamole, aggrenox, cilostazol, ifetroban, isbogrel, furegrelate, resveratrol, warfarin, and ozagrel; or

(iii) an injectable anticoagulant agent.

9. The compound of claim 2 wherein said compound is administered in

combination with

an antiplatelet agent; and

an anticoagulant agent.

10. The compound according to claim 9, wherein

(i) the antiplatelet agent is a cyclooxygenase inhibitor or acetylsalicylic acid; or

(ii) the anticoagulant agent is a factor Xa inhibitor, optionally betrixaban, or a pharmaceutically acceptable salt thereof, optionally wherein the pharmaceutically acceptable salt of betrixaban is the maleate salt.

11. The compound according to any one of claims 1 to 10, wherein both or all of the compound and the therapeutic agent(s) are administered in sub-therapeutic dosages.

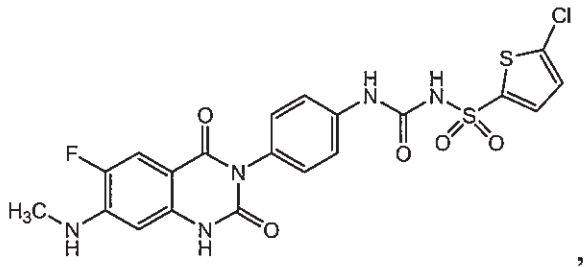
12. The compound according to any one of claims 1 to 11, wherein the compound and the therapeutic agent(s) are administered simultaneously or sequentially.

13. The compound according to any one of claims 1 to 12, wherein the pharmaceutically acceptable salt of [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea is the potassium salt or sodium salt.

14. The compound according to any one of claims 1 to 13, wherein said thrombosis-related condition is selected from the group consisting of acute myocardial infarction, unstable angina, chronic stable angina, transient ischemic attacks, strokes, peripheral vascular disease, preeclampsia/eclampsia, deep venous thrombosis, embolism, disseminated intravascular coagulation and thrombotic cytopenic purpura, thrombotic and restenotic complications following invasive procedures resulting from angioplasty, carotid endarterectomy, post CABG (Coronary arteryl bypass graft) surgery, vascular graft surgery, stent placements and insertion of endovascular devices and prosthesis.

15. A pharmaceutical composition, comprising a pharmaceutically acceptable

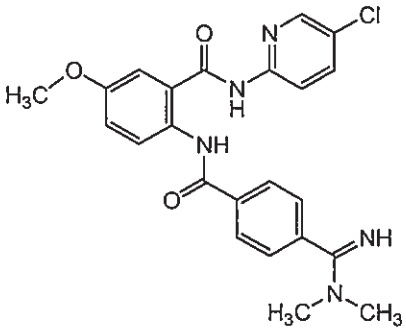
carrier and the following therapeutic agents: a first therapeutic which is [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, of the formula



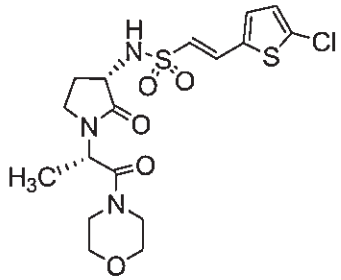
,

or a pharmaceutically acceptable salt thereof, and

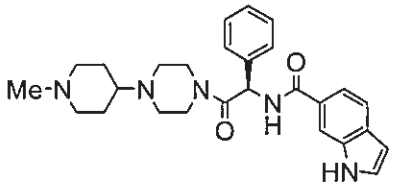
a second therapeutic agent selected from the group consisting of specific inhibitors of thrombin, specific inhibitors of factor IXa, specific inhibitors of factor XI, specific inhibitors of factor XIa, specific inhibitors of factor VIIa, lepirudin, phenocoumarol, synthetic pentasaccharides, dipyridamole, aggrenox, cilostazol, ifetroban, isbogrel, furegrelate, resveratrol, ozagrel, an anti-factor XI antibody, YM-150, Daiichi DU-176b, N-{(1R)-2-[4-(1-methyl-4-piperidinyl)-1-piperazinyl]-2-oxo-1-phenylethyl}-1H-indole-6-carboxamide, apixaban, rivaroxaban, otamixaban, razaxaban,



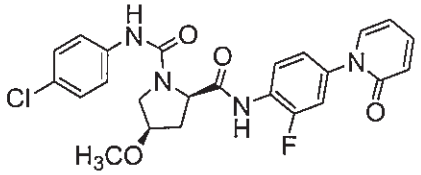
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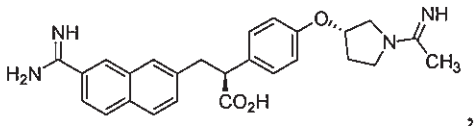
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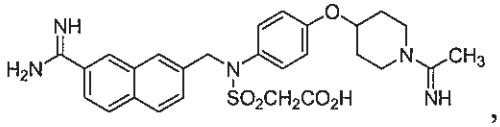
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and combinations thereof.

16. A pharmaceutical composition, comprising a pharmaceutically acceptable carrier and the following therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) a therapeutic agent selected from the group consisting of an anticoagulant agent, an antiplatelet agent and combinations thereof,

wherein at least one of the therapeutic agents is used in a sub-therapeutic dosage.

17. The pharmaceutical composition of claim 16, comprising

(a) a pharmaceutically acceptable carrier and the following two therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) an anticoagulant agent;

(b) a pharmaceutically acceptable carrier and the following two therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) another antiplatelet agent; or

(c) a pharmaceutically acceptable carrier and the following three

therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof;

(2) another antiplatelet agent; and

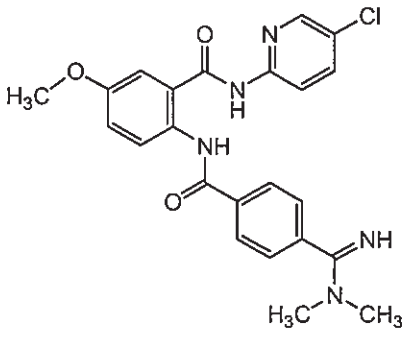
(3) an anticoagulant agent.

18. The pharmaceutical composition of any one of claims 15-17 wherein the therapeutic agents or the dosages of the therapeutic agents present in the composition is as defined in any one of claims 3 to 8, 10, and 11.

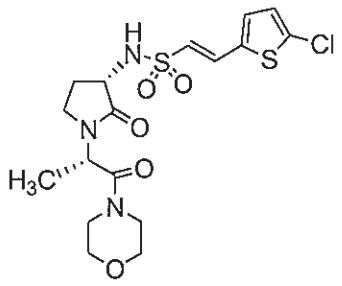
19. The therapeutic agents:

(1) a first therapeutic which is [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

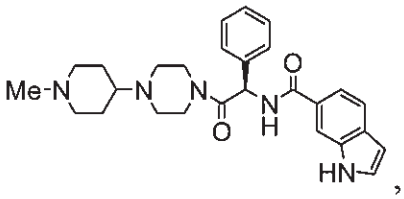
(2) a second therapeutic selected from the group consisting of specific inhibitors of thrombin, specific inhibitors of factor IXa, specific inhibitors of factor XI, specific inhibitors of factor XIa, specific inhibitors of factor VIIa, lepirudin, phenocoumarol, synthetic pentasaccharides, dipyridamole, aggrenox, cilostazol, ifetroban, isbogrel, furegrelate, resveratrol, ozagrel, an anti-factor XI antibody, YM-150, Daiichi DU-176b, N-{(1R)-2-[4-(1-methyl-4-piperidinyl)-1-piperazinyl]-2-oxo-1-phenylethyl}-1H-indole-6-carboxamide, apixaban, rivaroxaban, otamixaban, razaxaban,



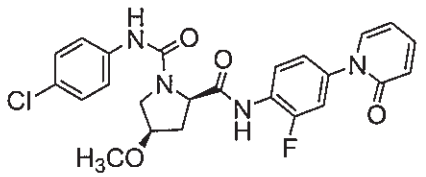
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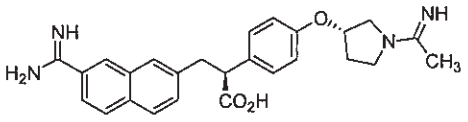
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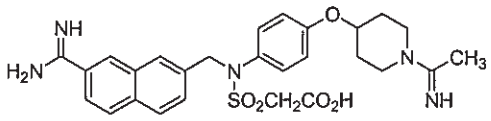
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and combinations thereof,

which are formulated into two separate pharmaceutical compositions for simultaneous or sequential administration to a mammal for the treatment of a condition characterized by undesired thrombosis.

20. The therapeutic agents:

(1) [4-(6-fluoro-7-methylamino-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-phenyl]-5-chloro-thiophen-2-yl-sulfonylurea, or a pharmaceutically acceptable salt thereof; and

(2) a therapeutic selected from the group consisting of an anticoagulant agent , an antiplatelet agent and combinations thereof,

which are formulated into two separate pharmaceutical compositions for simultaneous or sequential administration to a mammal for the treatment of a condition characterized by undesired thrombosis,

wherein at least one of the therapeutic agents is used in a sub-therapeutic dosage.