CLAIMS:

1. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use in reducing a cardiovascular event in a subject, wherein the subject is a subject with a history of a previous cardiovascular event or a history of at least one risk factor for cardiovascular disease, and wherein the cardiovascular event is acute coronary syndrome.

2. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 1, wherein the subject is a subject with a history of a previous cardiovascular event, and wherein the cardiovascular event is acute coronary syndrome.

3. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 2, wherein said subject also has a history of at least one risk factor for cardiovascular disease.

4. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 1 or 3, wherein the risk factor is manifest coronary heart disease, coronary artery disease, thrombosis, transient ischaemic attack, left ventricular hypertrophy, arteriosclerosis, restenosis, tobacco smoking or peripheral vascular disease, or wherein the risk factor is elevated triglycerides, systemic inflammation, high blood phosphorus levels, high parathyroid hormone levels, microalbuminuria, or high homocysteine levels, or wherein the risk factor is obesity, hyperglycemia, chronic renal failure, high blood glucose, chronic kidney disease, or metabolic syndrome, or wherein the risk factor is hypertension, dyslipidemia, hyperlipidemia, elevated total cholesterol, elevated LDL cholesterol, or low HDL cholesterol or atherosclerosis.

5. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 1 or 2, wherein the subject has elevated levels of C-

reactive protein (CRP), wherein the subject is older than 55 years, wherein the subject is non-hypertensive, wherein the subject has diabetes mellitus, or wherein the subject has a history of two or more said risk factors.

6. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 1, wherein said risk factor is not any of Type 2 diabetes, obesity, hyperglycemia, dyslipidemia, hyperlipidemia, chronic renal failure, high blood glucose, chronic kidney disease, hypertension, atherosclerosis or metabolic syndrome.

7. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 6, wherein the cardiovascular event is acute coronary syndrome.

8. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 7, wherein the subject is older than 55 years, or wherein the subject has a history of two or more said risk factors.

9. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use in reducing mortality following a cardiovascular event in a subject, wherein the cardiovascular event is acute coronary syndrome.

10. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 9, wherein the subject does not have Type 2 diabetes, wherein the subject has survived a previous cardiovascular event of myocardial infarction or stroke, wherein the subject is non-hypertensive or wherein the subject has a history of one or more risk factors for cardiovascular disease, wherein the risk factor is optionally manifest coronary heart disease, coronary artery disease, thrombosis, transient ischaemic attack, left ventricular hypertrophy, arteriosclerosis, restenosis, tobacco smoking, peripheral vascular disease, elevated triglycerides, systemic inflammation, high blood phosphorus levels, high parathyroid hormone levels, microalbuminuria, high

homocysteine levels, obesity, hyperglycemia, chronic renal failure, high blood glucose, chronic kidney disease, metabolic syndrome, hypertension, dyslipidemia, hyperlipidemia, elevated total cholesterol, elevated LDL cholesterol, or low HDL cholesterol or atherosclerosis.

11. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount and at least one other pharmaceutical composition comprising an active agent other than an IL-1β antibody or fragment for use in treating a cardiovascular event in a subject, wherein the cardiovascular event is acute coronary syndrome.

12 An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any one of claims 1, 2, 6, or 9, further comprising administering at least one other pharmaceutical composition comprising an active agent other than an anti-IL-1β binding antibody or binding fragment thereof.

13. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 11 or 12, wherein the active agent of said at least one other pharmaceutical composition is a cholesterol lowering agent, a statin, an HMG-CoA reductase inhibitor, a calcium channel blocker, a beta blocker, an antihypertensive, a diuretic, aspirin, niacin, an angiotensin-converting enzyme (ACE) inhibitor, an angiotensin II receptor blocker, a vasodilator, an anticoagulant, an inhibitor of platelet aggregation, a thrombolytic or digitalis.

14. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1, 6, 9, or 11, wherein said therapeutically effective amount of an anti-IL-1β binding antibody or binding fragment thereof is sufficient to achieve a decrease in CRP levels.

15. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody

or binding fragment thereof binds to human IL-1β with a dissociation constant of about 500 pM or less.

16. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody or binding fragment thereof is a neutralizing antibody.

17. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to an IL-1β epitope such that the bound antibody or fragment substantially permits the binding of IL-1β to IL-1 receptor I (IL-1RI).

18. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody or binding fragment thereof competes with the binding of an antibody having the light chain variable region of SEQ ID NO:1 and the heavy chain variable region of SEQ ID NO:2

19. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to an epitope incorporating Glu64 of IL-1β.

20. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to amino acids 1-34 of the N terminus of IL-1β.

21. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 1 mg/kg or less of antibody or fragment, wherein the one or more doses are at least 0.01 mg/kg of antibody or fragment.

22. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 0.03 mg/kg to 1 mg/kg.

23. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-14, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered as a fixed dose, independent of a dose per subject weight ratio.

24. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 14, wherein the anti-IL-1β binding antibody or binding fragment thereof is administered in one or more doses of 100 mg or less of antibody or fragment., wherein the anti-IL-1β binding antibody or binding fragment thereof is administered in one or more doses of at least 0.5 mg of antibody or fragment.

25. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-24, wherein the anti-IL-1β binding antibody or binding fragment thereof is administered by subcutaneous, intravenous or intramuscular injection.

26. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of any of claims 1-25, wherein administration of an initial dose of anti-IL-1β binding antibody or binding fragment thereof is followed by the administration of one or more subsequent doses.

27. An anti-IL-1β binding antibody or binding fragment thereof in a therapeutically effective amount for use of claim 26, wherein said initial dose and one or more subsequent doses are administered at an interval of about once every week to about once every 12 months.

CLAIMS:

1. Use of an anti-IL-1β binding antibody or binding fragment thereof, in the manufacture of a medicament for reducing a cardiovascular event in a subject, wherein the subject is a subject with a history of a previous cardiovascular event or a history of at least one risk factor for cardiovascular disease, and wherein the cardiovascular event is myocardial infarction, stroke, cardiovascular death, congestive heart failure, cardiac arrest, acute coronary syndrome, angina, or a revascularization procedure.

2. The use of claim 1, wherein the subject is a subject with a history of a previous cardiovascular event, and wherein the cardiovascular event is myocardial infarction, stroke, acute coronary syndrome, angina or a revascularization procedure.

3. The use of claim 1 or 2, wherein the revascularization procedure is a coronary, carotid or peripheral arterial revascularization procedure.

4. The use of claim 3, wherein the coronary, carotid or peripheral arterial revascularization procedure is a percutaneous coronary intervention (PCI), a stent implant, coronary artery bypass graft (CABG), carotid endarterectomy, peripheral vascular disease bypass surgery, or peripheral angioplasty surgery.

5. The use of claim 2, wherein said subject also has a history of at least one risk factor for cardiovascular disease.

6. The use of claim 1 or 5, wherein the risk factor is manifest coronary heart disease, coronary artery disease, thrombosis, transient ischaemic attack, left ventricular hypertrophy, arteriosclerosis, restenosis, tobacco smoking or peripheral vascular disease.

7. The use of claim 1 or 5, wherein the risk factor is elevated triglycerides, systemic inflammation, high blood phosphorus levels, high parathyroid hormone levels, microalbuminuria, or high homocysteine levels.

8. The use of claim 1 or 5, wherein the risk factor is obesity, hyperglycemia, chronic renal failure, high blood glucose, chronic kidney disease, or metabolic syndrome.

9. The use of claim 1 or 5, wherein the risk factor is hypertension, dyslipidemia, hyperlipidemia, elevated total cholesterol, elevated LDL cholesterol, or low HDL cholesterol or atherosclerosis.

10. The use of claim 1 or 2, wherein the subject has elevated levels of C-reactive protein (CRP).

11. The use of claim 1 or 2, wherein the subject is older than 55 years.

12. The use of claim 1 or 2, wherein the subject is non-hypertensive.

13. The use of claim 1 or 2, wherein the subject has diabetes mellitus.

14. The use of claim 13, wherein said diabetes mellitus is Type 2 diabetes.

15. The use of claim 1 or 2, wherein the subject has a history of two or more said risk factors.

16. The use of claim 15, wherein the subject has a history of three or more said risk factors.

17. The use of claim 1 or 2, wherein said anti-IL-1β binding antibody or binding fragment thereof is sufficient to achieve a decrease in CRP levels.

18. Use of an anti-IL-1β binding antibody or binding fragment thereof in the manufacture of a medicament for reducing mortality following a cardiovascular event in a subject.

19. The use of claim 18, wherein the cardiovascular event is myocardial infarction.

20. The use of claim 18, wherein the cardiovascular event is stroke.

21. The use of claim 18, wherein the cardiovascular event is congestive heart failure.

22. The use of claim 18, wherein the cardiovascular event is acute coronary syndrome.

23. The use of claim 18, wherein the cardiovascular event is angina.

24. The use of claim 18, wherein the cardiovascular event is a revascularization procedure.

25. The use of claim 24, wherein the revascularization procedure is a coronary, carotid or peripheral arterial revascularization procedure.

26. The use of claim 25, wherein the coronary, carotid or peripheral arterial revascularization procedure is a percutaneous coronary intervention (PCI), a stent implant, coronary artery bypass graft (CABG), carotid endarterectomy, peripheral vascular disease bypass surgery, or peripheral angioplasty surgery.

27. The use of claim 18, wherein the subject does not have Type 2 diabetes.

28. The use of claim 18, wherein the subject has survived a previous cardiovascular event of myocardial infarction or stroke.

29. The use of claim 18, wherein the occurrence of said cardiovascular event is a reoccurrence of a cardiovascular event of myocardial infarction or stroke.

30. The use of claim 18, wherein the subject has a history of one or more risk factors for cardiovascular disease.

31. The use of claim 30, wherein the risk factor is manifest coronary heart disease, coronary artery disease, thrombosis, transient ischaemic attack, left ventricular hypertrophy, arteriosclerosis, restenosis, tobacco smoking or peripheral vascular disease.

32. The use of claim 30, wherein the risk factor is elevated triglycerides, systemic inflammation, high blood phosphorus levels, high parathyroid hormone levels, microalbuminuria, or high homocysteine levels.

33. The use of claim 30, wherein the risk factor is obesity, hyperglycemia, chronic renal failure, high blood glucose, chronic kidney disease, or metabolic syndrome.

34. The use of claim 30, wherein the risk factor is hypertension, dyslipidemia, hyperlipidemia, elevated total cholesterol, elevated LDL cholesterol, or low HDL cholesterol or atherosclerosis.

35. The use of claim 18, wherein the subject is non-hypertensive.

36. The use of claim 30, wherein the subject has a history of two or more said risk factors.

37. The use of claim 36, wherein the subject has a history of three or more said risk factors.

38. The use of claim 18, wherein said anti-IL-1β binding antibody or binding fragment thereof is sufficient to achieve a decrease in CRP levels.

39. Use of an anti-IL-1β binding antibody or binding fragment thereof, in the manufacture of a medicament for reducing a cardiovascular event in a subject with a history of at least one risk factor for cardiovascular disease, wherein said risk factor is not Type 2 diabetes, obesity, hyperglycemia, dyslipidemia, hyperlipidemia, chronic renal failure, high blood glucose, chronic kidney disease, hypertension, atherosclerosis or metabolic syndrome.

40. The use of claim 39, wherein the risk factor is not Type 2 diabetes.

41. The use of claim 39 or 40, wherein the cardiovascular event is myocardial infarction.

42. The use of claim 39 or 40, wherein the cardiovascular event is stroke.

43. The use of claim 39 or 40, wherein the cardiovascular event is cardiac arrest.

44. The use of claim 39 or 40, wherein the cardiovascular event is congestive heart failure.

45. The use of claim 39 or 40, wherein the cardiovascular event is cardiovascular death.

46. The use of claim 39 or 40, wherein the cardiovascular event is acute coronary syndrome.

47. The use of claim 39 or 40, wherein the cardiovascular event is angina.

48. The use of claim 39 or 40, wherein the cardiovascular event is a revascularization procedure.

49. The use of claim 48, wherein the revascularization procedure is a coronary, carotid or peripheral arterial revascularization procedure.

50. The use of claim 49, wherein the coronary, carotid or peripheral arterial revascularization procedure is a percutaneous coronary intervention (PCI), a stent implant, coronary artery bypass graft (CABG), carotid endarterectomy, peripheral vascular disease bypass surgery, or peripheral angioplasty surgery.

51. The use of claim 39, wherein the risk factor is manifest coronary heart disease, coronary artery disease, thrombosis, transient ischaemic attack, left ventricular hypertrophy, arteriosclerosis, restenosis, tobacco smoking or peripheral vascular disease.

52. The use of claim 39, wherein the risk factor is elevated triglycerides, systemic inflammation, high blood phosphorus levels, high parathyroid hormone levels, microalbuminuria, or high homocysteine levels.

53. The use of claim 39, wherein the subject has elevated levels of C-reactive protein (CRP).

54. The use of claim 39, wherein the subject is older than 55 years.

55. The use of claim 39, wherein the subject has a history of two or more said risk factors.

56. The use of claim 55, wherein the subject has a history of three or more said risk factors.

57. The use of claim 39, wherein said anti-IL-1β binding antibody or binding fragment thereof is sufficient to achieve a decrease in CRP levels.

58. Use of an IL-1β binding antibody or binding fragment thereof and at least one other pharmaceutical composition comprising an active agent other than an IL-1β antibody or fragment thereof, in the manufacture of a medicament for treating a cardiovascular event in a subject, wherein the cardiovascular event is myocardial infarction, stroke, congestive heart failure, acute coronary syndrome or angina.

59. The use of claim 58, wherein the active agent of said at least one other pharmaceutical composition is a cholesterol lowering agent, a statin, an HMG-CoA reductase inhibitor, a calcium channel blocker, a beta blocker, an antihypertensive, a

diuretic, aspirin, niacin, an angiotensin-converting enzyme (ACE) inhibitor, an angiotensin II receptor blocker, a vasodilator, an anticoagulant, a inhibitor of platelet aggregation, a thrombolytic or digitalis.

Use of an anti-IL-1β binding antibody or binding fragment thereof, in the manufacture of a medicament for treating a cardiovascular event in a subject, wherein the cardiovascular event is myocardial infarction, stroke, congestive heart failure, acute coronary syndrome or angina, together with a revascularization procedure.

61. The use of claim 60, wherein the revascularization procedure is a coronary, carotid or peripheral arterial revascularization procedure.

62. Use of anti-IL-1β binding antibody or binding fragment thereof, in the manufacture of a medicament for reducing restenosis in a subject following a revascularization procedure.

63. The use of claim 62, wherein the revascularization procedure is a coronary, carotid or peripheral arterial revascularization procedure.

64. The use of any one of claims 58, 60 or 62, wherein said anti-IL-1β binding antibody or binding fragment thereof is sufficient to achieve a decrease in CRP levels.

65. Use of an anti-IL-1β binding antibody or binding fragment thereof and one or more antihypertensive agents, in the manufacture of a medicament for treating acute hypertension in a subject.

66. The use of claim 65, wherein the subject has a blood pressure of greater than or equal to 180/110 mm Hg.

67. The use of claim 65, wherein the antihypertensive agent is to be administered intravenously.

68. The use of claim 65, wherein the antihypertensive agent is labetalol, metoprolol, hydralazine, nitroglycerin, nicardipine, sodium nitroprusside or clevidipine.

69. The use of any one of claims 1, 2, 18, 39, 60 or 62, wherein said medicament is to be administered with at least one other pharmaceutical composition comprising an active agent other than an anti-IL-1β binding antibody or binding fragment thereof.

70. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is a cholesterol lowering agent.

71. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is a statin or an HMG-CoA reductase inhibitor.

72. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is a calcium channel blocker.

73. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is an antihypertensive, a diuretic or aspirin.

74. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker.

75. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is a vasodilator.

76. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is an anticoagulant or inhibitor of platelet aggregation.

77. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is a thrombolytic.

78. The use of claim 69, wherein the active agent of said at least one other pharmaceutical composition is digitalis.

79. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to human IL-1β with a dissociation constant of about 500 pM or less.

80. The use of claim 79, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to human IL-1β with a dissociation constant of about 50 pM or less.

81. The use of claim 80, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to human IL-1β with a dissociation constant of about 5 pM or less.

82. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof is a neutralizing antibody.

83. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to an IL-1β epitope such that the bound antibody or fragment substantially permits the binding of IL-1β to IL-1 receptor I (IL-1RI).

84. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof does not detectably bind to IL-1α, IL-1R or IL-1Ra.

85. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof competes with the binding of an antibody having the light chain variable region of SEQ ID NO:1 and the heavy chain variable region of SEQ ID NO:2

86. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to an epitope incorporating Glu64 of IL-1β.

87. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof binds to amino acids 1-34 of the N terminus of IL-1β.

88. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof is humanized or human.

89. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 1 mg/kg or less of antibody or fragment.

90. The use of claim 89, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 0.3 mg/kg or less of antibody or fragment.

91. The use of claim 90, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 0.03 mg/kg or less of antibody or fragment.

92. The use of any one of claims 89-91, wherein the one or more doses are at least 0.01 mg/kg of antibody or fragment.

93. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 0.03 mg/kg to 1 mg/kg.

94. The use of any one of claims 1-78, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered as a fixed dose, independent of a dose per subject weight ratio.

95. The use of claim 94, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 100 mg or less of antibody or fragment.

96. The use of claim 95, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 25 mg or less of antibody or fragment.

97. The use of claim 96, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 10 mg or less of antibody or fragment.

98. The use of any one of claims 94-97, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of at least 0.5 mg of antibody or fragment.

99. The use of claim 94 wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered in one or more doses of 1 mg to 100 mg of antibody or fragment.

100. The use of any one of claims 94-99, wherein said fixed dose of anti-IL-1β binding antibody or binding fragment thereof is to be administered using a pre-filled syringe or delivery device.

101. The use of any one of claims 1-100, wherein the anti-IL-1β binding antibody or binding fragment thereof is to be administered by subcutaneous, intravenous or intramuscular injection.

102. The use of any one of claims 1-101, wherein administration of an initial dose of anti-IL-1β binding antibody or binding fragment thereof is followed by the administration of one or more subsequent doses.

103. The use of claim 102, wherein said initial dose and one or more subsequent doses are to be administered at an interval of about once every week to about once every 12 months.

104. The use of claim 103, wherein said initial dose and one or more subsequent doses are to be administered at an interval of about once every two weeks to about once every 6 months.

105. The use of claim 104, wherein said initial dose and one or more subsequent doses are to be administered at an interval of about once every month to about once every 6 months.

106. The use of claim 105, wherein said initial dose and one or more subsequent doses are to be administered at an interval of about once every month to about once every 3 months.

107. The use method of claim 105, wherein said initial dose and one or more subsequent doses are to be administered at an interval of about once every 3 months to about once every 6 months.