Claims:

1. Use of menaquinone-7 (MK-7) and/or menaquinol-7 (MKH2-7) in the manufacture of a pharmaceutical composition for treating tissue calcification in a pre-diabetic subject or a subject with diabetes, or with chronic kidney disease, or at risk of cardiovascular disease or a combination thereof, and in need thereof, wherein the composition is administered to the subject for at least 6 weeks, with at least 2 mg of the MK7 and/or MKH2-7 being administered per day, and wherein said administration of the MK7 and/or MKH2-7:

(i) increases a plasma level of Fetuin A relative to the plasma level of Fetuin A prior to administration; or

(ii) decreases a plasma level of Highly Sensitive C Reactive Protein (hs-CRP) relative to the plasma level of hs-CRP prior to administration.

2. The use of claim 1, wherein the subject has diabetes, such as type II diabetes, or has been diagnosed as pre-diabetic.

3. The use of claim 1, wherein the subject

has chronic kidney disease; or

has stage 4 or 5 chronic kidney disease/end stage renal disease.

4. The use of claim 1, wherein the subject is undergoing hemodialysis.

5. The use of claim 1, wherein the subject is receiving non-warfarin-based anti-coagulant therapy, such as oral anti-coagulation therapy, and optionally wherein the anti-coagulation therapy comprises an inhibitor of Factor Xa activity or Factor IIa activity.

6. Use of menaquinone-7 (MK-7) and/or menaquinol-7 (MKH2-7) in the manufacture of a pharmaceutical composition for treating tissue calcification in a subject in need thereof, wherein administration of the composition to the subject for at least 6 weeks, with at least 2 mg of the MK7 and/or MKH2-7 being administered per day, causes at least one of the following:

(i) increase the subject’s serum T50 value relative to the subject’s serum T50 value prior to administration of the MK-7 and/or MKH2-7,

(ii) increase a ratio of a carboxylated to a non-carboxylated form of a Vitamin K-dependent protein in the subject’s plasma relative to the ratio prior to administration of the MK-7 and/or MKH2-7,

°°

(iii) increase the plasma level of Fetuin A relative to the plasma concentration of Fetuin A prior to administration of the MK-7 and/or MKH2-7, or

(iv) decrease the plasma level of D-Dimer or Highly Sensitive C Reactive Protein relative to the plasma concentration of D-Dimer or Highly Sensitive C Reactive Protein (hs-CRP) prior to administration of the MK-7 and/or MKH2-7, thereby to treat tissue calcification in the subject; and wherein the subject:

(i) has diabetes;

(ii) has been diagnosed as pre-diabetic;

(iii) has chronic kidney disease; or

(iv) is undergoing hemodialysis.

7. The use of claim 6, wherein the subject is having stage 5 chronic kidney disease and undergoing oral, non-warfarin-based anticoagulant therapy, and in need thereof, and wherein upon administration of the MK7 and/or MKH2-7:

(i) increases a plasma level of Fetuin A relative to the plasma level of Fetuin A prior to administration; or

(ii) decreases a plasma level of Highly Sensitive C Reactive Protein (hs-CRP) relative to the plasma level of hs-CRP prior to administration.

8. The use of claim 7, wherein the subject:

(i) is diabetic;

(ii) has been diagnosed as pre-diabetic; or

(iii) is undergoing hemodialysis.

9. The use of claim 7, wherein the anti-coagulation therapy comprises an inhibitor of Factor Xa activity or Factor IIa activity.

10. The use of claim 1, whereupon administration of the MK-7 and/or MKH2-7 to the subject increases the subject’s serum T50 value relative to the subject’s serum T50 value prior to administration of the MK-7 and/or MKH2-7.

11. The use of claim 1, wherein administration of the MK-7 and/or MKH2-7:

(a) increases a ratio of a carboxylated to a non-carboxylated of a Vitamin K dependent protein; or

°°

(b) decreases an amount of a non-carboxylated Vitamin K dependent protein in plasma of the subject relative to the ratio or amount present prior to administration of the MK-7 and/or MKH2-7.

12. The use of claim 11, wherein the Vitamin K-dependent protein is selected from Matrix Gla Protein, Growth Arrest Specific Gene 6 (Gas-6) protein, PIVKA-II protein, osteocalcin, activated Protein C, or activated Protein S.

13. The use of claim 1, wherein upon administration of the MK-7 and/or MKH2-7 to the subject decreases a plasma level of D-Dimer or Highly Sensitive C Reactive Protein (hs-CRP) relative to the plasma level of D-Dimer or Highly Sensitive C Reactive Protein (hs-CRP) prior to administration of the MK-7 and/or MKH2-7.

14. The use of claim 1, wherein, when the subject has a dermal lesion and/or vascular lesion, the administration of the MK-7 and/or MKH2-7 reduces the size of the dermal and/or vascular lesion.