is 0.01 mg/mL to 2.0 mg/mL, 0.1 mg/mL to 0.5 mg/mL, or 0.1 mg/mL to 0.4 mg/mL. In certain embodiments, 12 months after administration of the pharmaceutical composition, vessel cross-sectional area at the disease site has decreased no more than 60%, 50%, or 30%, when compared to vessel cross-sectional area at the disease site at the time of administration. In a certain embodiment, the composition further comprises a contrast medium for visualizing the injection. In a certain embodiment, the artery is below the knee. In a certain embodiment, the artery is in the leg above the knee. In a certain embodiment, the blood vessel is below-knee popliteal vessel or tibial vessel.

[0009a] In another aspect, described herein is a use of a pharmaceutical composition comprising temsirolimus or its pharmaceutically acceptable salts thereof in the manufacture of a medicament for the treatment of a peripheral artery disease or restenosis in a peripheral artery in a human subject in need thereof, wherein a therapeutically effective amount of the medicament is to be administered to the subject, wherein the medicament is to be administered by adventitial delivery to the peripheral artery or by direct injection to or near a disease site in a tissue surrounding a wall of a peripheral artery or in the wall of the peripheral artery via a laterally extending injection needle of a catheter advanced through vasculature of the human subject, wherein the amount of the medicament is therapeutically effective to cause patency at the disease site after administration to increase or minimally decrease when compared to patency at the disease site at the time of administration.

[0010] In another aspect, described herein, is an injectable composition comprising temsirolimus or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable excipient for use in treating restenosis in a peripheral artery of a human subject, wherein the composition is suitable for adventitial delivery to the peripheral artery, wherein the composition is suitable for direct injection to a vascular disease site in a tissue surrounding a wall of the peripheral artery or in the wall of the peripheral artery via a laterally extending needle from a catheter advanced through vasculature of the human subject in a therapeutically effective amount effective to cause patency at the disease site after administration to increase or minimally decrease when compared to patency at the disease site at the time of administration. In a certain embodiment, the composition is suitable for adventitial delivery in the leg. In a certain embodiment, the composition is suitable for adventitial delivery below the knee. In a certain embodiment, the composition is suitable for adventitial delivery in the leg above the knee. In a certain embodiment, the composition is suitable for adventitial delivery to a below-knee popliteal or tibial vessel. In certain embodiments, the therapeutically effective amount of temsirolimus is

about 1 μg to 50 mg, about 10 μg to 20 mg, or about 25 μg to 10 mg. In certain embodiments, the injection volume of the composition is about 0.01 ml to about 50 ml, or about 0.5 ml to about 20 ml. In certain embodiments, the therapeutically effective amount of temsirolimus is about 0.005 mg to 5 mg per cm, or about 0.025 mg to 1 mg per cm of longitudinal length of the disease site in the blood vessel. In certain embodiments, the concentration of temsirolimus is about 0.01 mg/mL to about 2.0 mg/mL, about 0.1 mg/mL to about 0.5 mg/mL, or about 0.1 mg/mL to about 0.4 mg/mL. In a certain embodiment, the pharmaceutically acceptable excipient is 0.9% sodium chloride injection USP, dehydrated alcohol, dl-alpha tocopherol, anhydrous citric acid, polysorbate 80, polyethylene glycol 400, propylene glycol, or a combination thereof.

CLAIMS

WHAT IS CLAIMED IS:

1. Use of a pharmaceutical composition comprising temsirolimus or its pharmaceutically acceptable salts thereof in the manufacture of a medicament for the treatment of a peripheral artery disease or restenosis in a peripheral artery in a human subject in need thereof, wherein a therapeutically effective amount of the medicament is to be administered to the subject, wherein the medicament is to be administered by adventitial delivery to the peripheral artery or by direct injection to or near a disease site in a tissue surrounding a wall of a peripheral artery or in the wall of the peripheral artery via a laterally extending injection needle of a catheter advanced through vasculature of the human subject, wherein the amount of the medicament is therapeutically effective to cause patency at the disease site after administration to increase or minimally decrease when compared to patency at the disease site at the time of administration.
2. The use of claim 1, wherein the therapeutically effective amount of temsirolimus is about 1 μg to 50 mg.
3. The use of either claim 1 or 2, wherein the therapeutically effective amount of temsirolimus is about 10 μg to 20 mg.
4. The use of any one of claims 1 to 3, wherein the therapeutically effective amount of temsirolimus is about 25 μg to 10 mg.
5. The use of any one of claims 1 to 4, wherein the therapeutically effective amount of temsirolimus is about 0.005 mg to 5 mg per cm of longitudinal length of the disease site in the peripheral artery.
6. The use of any one of claims 1 to 5, wherein the therapeutically effective amount of temsirolimus is about 0.025 mg to 1 mg per cm of longitudinal length of the disease site in the peripheral artery.
7. The use of any one of claims 1 to 6, wherein the injection volume of the medicament is about 0.01 ml to about 50 ml.
8. The use of any one of claims 1 to 7, wherein the injection volume of the medicament is about 0.5 ml to about 20 ml.
9. The use of any one of claims 1 to 8, wherein the concentration of temsirolimus is 0.01 mg/mL to 2.0 mg/mL.
10. The use of any one of claims 1 to 8, wherein the concentration of temsirolimus is 0.1 mg/mL to 0.5 mg/mL.

11. The use of any one of claims 1 to 8, wherein the concentration of temsirolimus is 0.1 mg/mL to 0.4 mg/mL.

12. The use of any one of claims 1 to 11, wherein 12 months after administration of the medicament, vessel cross-sectional area at the disease site has decreased no more than 60%, when compared to vessel cross-sectional area at the disease site at the time of administration.

13. The use of any one of claims 1 to 11, wherein 12 months after administration of the medicament, vessel cross-sectional area at the disease site has decreased no more than 50%, when compared to vessel cross-sectional area at the disease site at the time of administration.

14. The use of any one of claims 1 to 11, wherein 12 months after administration of the medicament, vessel cross-sectional area at the disease site has decreased no more than 30%, when compared to vessel cross-sectional area at the disease site at the time of administration.

15. The use of any one of claims 1 to 14, wherein the medicament further comprises a contrast medium for visualizing the injection.

16. The use of any one of claims 1 to 15, wherein the artery is in the leg.

17. The use of any one of claims 1 to 16, wherein the artery is below the knee.

18. The use of any one of claims 1 to 17, wherein the artery is in the leg above the knee.

19. The use of any one of claims 1 to 18, wherein the artery is below-knee popliteal vessel or tibial vessel.

20. The use of any one of claims 1 to 19, wherein the composition further comprises a pharmaceutically acceptable excipient, wherein the pharmaceutically acceptable excipient is 0.9% sodium chloride injection USP, dehydrated alcohol, *dl*-alpha tocopherol, anhydrous citric acid, polysorbate 80, polyethylene glycol 400, propylene glycol, or a combination thereof.