TITLE OF THE INVENTION

METHODS OF TREATING HYPERTRIGLYCERIDEMIA

PRIORITY CLAIM

[0001] This application claims priority to U.S. provisional application Serial No. 61/151,291 filed February 10, 2009 and U.S. provisional application Serial No. 61/173,755 filed April 29, 2009, each of which are incorporated by reference herein in their entireties.

BACKGROUND

[0002] Cardiovascular disease is one of the leading causes of death in the United States and most European countries. It is estimated that over 70 million people in the United States alone suffer from a cardiovascular disease or disorder including but not limited to high blood pressure, coronary heart disease, dislipidemia, congestive heart failure and stroke. A need exists for improved treatments for cardiovascular diseases and disorders.

SUMMARY

[0002a] In one aspect, the present disclosure refers to use of a composition comprising about 4 g of ethyl eicosapentaenoate and substantially no docosahexaenoic acid, in the manufacture of a medicament for treating moderate to severe hypertriglyceridemia in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl, wherein the composition is to be administered to the subject once per day.

[0002b] In another aspect, the present disclosure refers to use of a composition comprising at least about 96%, by weight, of all fatty acids present in the composition, ethyl eicosapentaenoate and the composition comprises not more than about 4%, by weight, of total fatty acids other than ethyl eicosapentaenoate, and the composition contains about 0.1% to about 0.6% of at least one fatty acid other than ethyl eicosapentaenoate and docosahexaenoic acid in the manufacture of a medicament for treating moderate to severe hypertriglyceridemia in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl, and wherein 4 capsules, each containing 1g of the composition, are to be administered to the subject daily.

[0003] In various embodiments, the present invention provides methods of treating and/or preventing cardiovascular-related diseases and, in particular, a method of blood lipid therapy comprising administering to a subject in need thereof a pharmaceutical composition

comprising eicosapentaenoic acid or a derivative thereof. In one embodiment, the composition contains not more than 10%, by weight, docosahexaenoic acid or derivative thereof, substantially no docosahexaenoic acid or derivative thereof, or no docosahexaenoic acid or derivative thereof. In another embodiment, eicosapentaenoic acid ethyl ester comprises at least 96%, by weight, of all fatty acids present in the composition; the composition contains not more than 4%, by weight, of total fatty acids other than eicosapentaenoic acid ethyl ester; and/or the composition contains about 0.1% to about 0.6% of at least one fatty acid other than eicosapentaenoic acid ethyl ester and docosahexaenoic acid (or derivative thereof).

[0004] In one embodiment, a pharmaceutical composition useful in accordance with the invention comprises, consists of or consists essentially of at least 95% by weight ethyl eicosapentaenoate (EPA-E), about 0.2% to about 0.5% by weight ethyl octadecatetraenoate (ODTA-E), about 0.05% to about 0.25% by weight ethyl nonaecapentaenoate (NDPA-E), about 0.2% to about 0.45% by weight ethyl arachidonate (AA-E), about 0.3% to about 0.5%

CLAIMS

What is claimed is:

1. Use of a composition comprising about 4 g of ethyl eicosapentaenoate and substantially no docosahexaenoic acid, in the manufacture of a medicament for treating moderate to severe hypertriglyceridemia in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl, wherein the composition is to be administered to the subject once per day.

2. Use of a composition comprising at least about 96%, by weight, of all fatty acids present in the composition, ethyl eicosapentaenoate and the composition comprises not more than about 4%, by weight, of total fatty acids other than ethyl eicosapentaenoate, and the composition contains about 0.1% to about 0.6% of at least one fatty acid other than ethyl eicosapentaenoate and docosahexaenoic acid in the manufacture of a medicament for treating moderate to severe hypertriglyceridemia in a subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl, and wherein 4 capsules, each containing 1g of the composition, are to be administered to the subject daily.

3. The use of claim 1 or claim 2, wherein the composition is useful for reducing triglycerides in the subject compared to placebo.

4. The use of claim 1 or claim 2, wherein the compositionis useful for reducing triglycerides in the subject compared to baseline.

5. The use of claim 4, wherein the compositionis useful for reducing triglycerides in the subject by at least about 25% compared to baseline.

6. The use of claim 1 or claim 2, wherein the compositionis useful for reducing triglycerides in the subject compared to a second subject having a fasting baseline triglyceride level of 500 mg/dl to about 1500 mg/dl who has not been administered the composition.

7. The use of claim 6, wherein the compositionis useful for reducing triglycerides in the subject by at least about 20% compared to the second subject.

8. The use of any one of claims 1 to 6, wherein the compositionis useful for reducing an apolipoprotein B level in the subject.

9. The use of any one of claims 1 to 6, wherein the compositionis useful for not substantially increasing an LDL-C level in the subject.

10. The use of claim 9, wherein the compositionis useful for reducing the LDL-C level in the subject.

11. The use of claim 4 or claim 5, wherein the compositionis useful for increasing an LDL-C level in the subject by no more than 5%.

12. The use of any one of claims 1 to 6, wherein the compositionis useful for reducing a VLDL-C level in the subject.

13. The use of any one of claims 1 to 6, wherein the compositionis useful for reducing a high-sensitivity C-reactive protein level in the subject.

14. The use of any one of claims 1 to 6, wherein the subject is to be administered the composition daily for a period of at least 12 weeks.

15. The use of claim 1, wherein the composition comprises at least about 90%, by weight, of all fatty acids present, ethyl eicosapentaenoate.

16. The use of claim 15, wherein the composition comprises at least about 95%, by weight, of all fatty acids present, ethyl eicosapentaenoate.

17. The use of claim 15, wherein the composition comprises at least about 96%, by weight, of all fatty acids present, ethyl eicosapentaenoate.

18. The use of claim 2, wherein the composition comprises less than about 3%, by weight, of all fatty acids present, docosahexaenoic acid.

19. The use of claim 2, wherein the composition comprises substantially no docosahexaenoic acid or its esters.

20. The use of any one of claims 1 to 19, wherein the subject is not to be administered an additional lipid lowering drug.

21. The use of any one of claims 1 to 19, wherein the subject is to be further administered an additional lipid lowering drug.

22. The use of claim 21, wherein the additional lipid lowering drug is a statin.

23. The use of any one of claims 1 to 22, wherein the subject is diabetic.