COMPOSITIONS FOR THE TREATMENT OF SKIN CONDITIONS

[0001] This application claims benefit of U.S. Provisional Application No. 62/659,566, filed on April 18, 2018, and U.S. Provisional Application No. 62/703,742, filed on July 26, 2018, both of which are incorporated herein by reference in their entirety.

SEQUENCE LISTING

[0002] The instant application contains a Sequence Listing which has been submitted in ASCII Format via EFS-Web and is hereby incorporated by reference in its entirety. Said ASCII copy, created on April 16, 2019, is named 53654-705_601_SL.txt and is 2,122 bytes in size.

BACKGROUND

[0003] Dysbiosis of the skin microbiome is associated with a variety of diseases where the skin barrier is disrupted and inflammation at the site of disruption may be increased as well. For example, in the case of atopic dermatitis, the skin microbiome of healthy subjects is significantly different from that of atopic dermatitis subjects. Symptoms of atopic dermatitis are often attributed to loss of commensal diversity. Microbiota dysfunction is also a feature of atopic dermatitis pathology. Overgrowth and infection of *Staphylococcus aureus* are contributors and consequences of immune imbalance and poor barrier function. Antibiotic treatments that mitigate growth of *S. aureus* can improve atopic dermatitis symptoms, but often cannot normalize the underlying pathology. Thus, there is a need for improved therapies for treatment of skin diseases associated with dysbiosis.

BRIEF SUMMARY

[0003a] In one aspect, the present disclosure refers to a use of a pharmaceutical composition in the manufacture of a medicament for the treatment of a skin condition associated with inflammation or skin barrier disruption, wherein the pharmaceutical composition comprises:

a) at least one strain of gram negative bacteria isolated or propagated from skin of a donor, wherein the at least one strain of gram negative bacteria is viable and purified; and
b) at least one strain of gram positive bacteria isolated or propagated from skin of a donor, wherein the at least one strain of gram positive bacteria is viable and purified,

wherein the medicament is to be topically administered in an amount sufficient for treatment of a skin condition associated with inflammation or skin barrier disruption.

[0003b] In another aspect, the present disclosure refers to a use of a pharmaceutical composition in the manufacture of a medicament for the treatment of a skin condition associated with inflammation or skin barrier disruption, wherein the pharmaceutical composition comprises at

least one strain of *Roseomonas mucosa* present in an amount sufficient for treatment of a skin condition associated with inflammation or skin barrier disruption to a subject in need thereof, wherein the at least one strain of *Roseomonas mucosa* is viable and purified.

[0003c] In yet another aspect, the present disclosure refers to a pharmaceutical composition, comprises: a mixture of bacteria, wherein the mixture comprises:

a) at least one strain of *Roseomonas mucosa* isolated or propagated from skin of a donor, wherein the at least one strain of *Roseomonas mucosa* is viable and purified; and
b) at least one strain of gram positive bacteria isolated or propagated from skin of a donor, wherein the at least one strain of gram positive bacteria is viable and purified,

wherein the at least one strain of *Roseomonas mucosa* and the at least one strain of gram positive bacteria are present in an amount sufficient for treatment of a skin condition associated with inflammation or skin barrier disruption in a subject in need thereof, and wherein the pharmaceutical composition is in a topical dosage form.

[0003d] In a further aspect, the present disclosure refers to a use of a pharmaceutical composition in the manufacture of a medicament for the treatment of a skin condition associated with inflammation or skin barrier disruption, wherein the pharmaceutical composition comprises:

a) at least one strain of *Roseomonas mucosa* isolated or propagated from a donor, wherein the at least one strain of *Roseomonas mucosa* is viable and purified; and
b) at least one strain of gram positive bacteria isolated or propagated from a donor;

wherein the at least one strain of *Roseomonas mucosa* and the at least one strain of gram positive bacteria are present in an amount sufficient for treatment of a skin condition associated with inflammation or skin barrier disruption in a subject in need thereof, and wherein the medicament is in a topical dosage form.

[0004] Provided herein is a pharmaceutical composition comprising: at least one strain of *Roseomonas mucosa* bacterium present in an amount sufficient for treatment of atopic dermatitis in a subject in need thereof, wherein the pharmaceutical composition is in an oral or rectal dosage form. Further provided herein are compositions, wherein the at least one strain of *Roseomonas mucosa* is viable. Further provided herein are compositions, wherein the at least one strain of *Roseomonas mucosa* is purified. Further provided herein are compositions, wherein the at least one strain of *Roseomonas mucosa* is isolated. Further provided herein are compositions, wherein the *Roseomonas mucosa* is present in an amount sufficient for a reduction in *Staphylococcus aureus* in the subject. Further provided herein are compositions, wherein the pharmaceutical composition further comprises a pharmaceutically-acceptable carrier. Further provided herein are compositions, wherein the at least one strain of *Roseomonas* genus

CLAIMS

WHAT IS CLAIMED IS:

1. Use of a pharmaceutical composition in the manufacture of a medicament for the treatment of a skin condition associated with inflammation or skin barrier disruption, wherein the pharmaceutical composition comprises:
    a) at least one strain of gram negative bacteria isolated or propagated from skin of a donor, wherein the at least one strain of gram negative bacteria is viable and purified; and
    b) at least one strain of gram positive bacteria isolated or propagated from skin of a donor, wherein the at least one strain of gram positive bacteria is viable and purified,

    wherein the medicament is to be topically administered in an amount sufficient for treatment of a skin condition associated with inflammation or skin barrier disruption.
2. The use of claim 1, wherein the skin condition associated with inflammation or skin barrier disruption is psoriasis, vitiligo, rosacea, eczema, allergic eczema, flexural eczema, infantile eczema, nummular eczema, discoid lupus, prurigo Besnier, or acne.
3. The use of claim 1, wherein the at least one species of gram negative bacteria comprises at least 2, 3, 4 or 5 different strains of gram negative bacteria.
4. The use of claim 1, wherein the at least one species of gram negative bacteria is present in an amount of from 10^2 to 10^{12} colony forming units.
5. The use of claim 1, wherein the at least one species of gram negative bacteria is to be administered to the subject at least two times per week.
6. The use of claim 1, wherein the at least one species of gram negative bacteria is to be administered to the subject every other day over a week.
7. The use of claim 1, wherein the at least one species of gram negative bacteria is to be administered to the subject once a day.
8. The use of claim 1, wherein the subject is an adult.
9. The use of claim 1, wherein the subject is a child.
10. The use of claim 1, wherein the subject is an infant.
11. Use of a pharmaceutical composition in the manufacture of a medicament for the treatment of a skin condition associated with inflammation or skin barrier disruption, wherein the pharmaceutical composition comprises at least one strain of *Roseomonas mucosa* present in an amount sufficient for treatment of a skin condition associated with

inflammation or skin barrier disruption to a subject in need thereof, wherein the at least one strain of *Roseomonas mucosa* is viable and purified.

12. The use of claim 11, wherein the skin condition associated with inflammation or skin barrier disruption is psoriasis, vitiligo, rosacea, discoid lupus, prurigo Besnier, or acne.
13. The use of claim 11, wherein the pharmaceutical composition further comprises a pharmaceutically acceptable carrier.
14. The use of claim11, wherein the at least one strain of *Roseomonas mucosa* is isolated.
15. The use of claim 11, wherein the at least one strain of *Roseomonas mucosa* is present in an amount of from 10^2 to 10^{12} colony forming units.
16. The use of claim 11, wherein the at least one strain of *Roseomonas mucosa* is present in an amount sufficient for a reduction in *Staphylococcus aureus* in the subject.
17. The use of claim 11, wherein the pharmaceutical composition is to be administered topically.
18. The use of claim 11, wherein the pharmaceutical composition is to be administered to the subject at least two times per week.
19. The use of claim 11, wherein the pharmaceutical composition is to be administered to the subject every other day over a week.
20. The use of claim 11, wherein the pharmaceutical composition is to be administered to the subject once a day.
21. The use of claim 11, wherein the subject is an adult.
22. The use of claim 11, wherein the subject is a child.
23. The use of claim 11, wherein the subject is an infant.
24. The use of claim 11, wherein the at least one strain of *Roseomonas mucosa* is derived from skin of a donor.
25. The use of claim 24, wherein the donor does not have psoriasis.
26. The use of any one of claims 11-25, wherein the at least one strain of *Roseomonas mucosa* comprises a nucleic acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.
27. A pharmaceutical composition, comprises: a mixture of bacteria, wherein the mixture comprises:
    a) at least one strain of *Roseomonas mucosa* isolated or propagated from skin of a donor, wherein the at least one strain of *Roseomonas mucosa* is viable and purified; and

b) at least one strain of gram positive bacteria isolated or propagated from skin of a donor, wherein the at least one strain of gram positive bacteria is viable and purified,

wherein the at least one strain of *Roseomonas mucosa* and the at least one strain of gram positive bacteria are present in an amount sufficient for treatment of a skin condition associated with inflammation or skin barrier disruption in a subject in need thereof, and wherein the pharmaceutical composition is in a topical dosage form.

28. The pharmaceutical composition of claim 27, wherein the pharmaceutical composition further comprises a pharmaceutically acceptable carrier.
29. The pharmaceutical composition of claim 27, wherein the skin condition associated with inflammation or skin barrier disruption is psoriasis, vitiligo, dermatitis, perioral dermatitis, neurodermatitis, seborrheic dermatitis, rosacea, discoid lupus, prurigo Besnier, or acne.
30. The pharmaceutical composition of claim 27, wherein the skin condition associated with inflammation or skin barrier disruption is psoriasis.
31. The pharmaceutical composition of claim 27, wherein the at least one strain of gram positive bacteria is of the genus *Staphylococci*, *Streptococci*, *Enterococci*, *Corynebacteriae*, or *Propionibacterii*.
32. The pharmaceutical composition of claim 27, wherein the at least one strain of gram positive bacteria is *Staphylococcus epidermis, Staphylococcus cohnii, or Staphylococcus hominis.*
33. The pharmaceutical composition of claim 27, wherein the *Roseomonas mucosa* is isolated.
34. The pharmaceutical composition of claim 27, wherein the *Roseomonas mucosa* is present in an amount of from 10^2 to 10^{12} colony forming units.
35. The pharmaceutical composition of claim 27, wherein *Roseomonas mucosa* is present in an amount sufficient for a reduction in *Staphylococcus aureus* in the subject.
36. The pharmaceutical composition of claim 27, wherein the at least one strain of *Roseomonas mucosa* comprises a nucleic acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.
37. Use of a pharmaceutical composition in the manufacture of a medicament for the treatment of a skin condition associated with inflammation or skin barrier disruption, wherein the pharmaceutical composition comprises:
    a) at least one strain of *Roseomonas mucosa* isolated or propagated from a donor, wherein the at least one strain of *Roseomonas mucosa* is viable and purified; and

b) at least one strain of gram positive bacteria isolated or propagated from a donor; wherein the at least one strain of *Roseomonas mucosa* and the at least one strain of gram positive bacteria are present in an amount sufficient for treatment of a skin condition associated with inflammation or skin barrier disruption in a subject in need thereof, and wherein the medicament is in a topical dosage form.

38. The use of claim 37, wherein the pharmaceutical composition further comprises a pharmaceutically acceptable carrier.
39. The use of claim 37, wherein the skin condition associated with inflammation or skin barrier disruption is psoriasis, vitiligo, dermatitis, perioral dermatitis, neurodermatitis, seborrheic dermatitis, rosacea, discoid lupus, prurigo Besnier, or acne.
40. The use of claim 37, wherein the skin condition associated with inflammation or skin barrier disruption is psoriasis.
41. The use of claim 37, wherein the at least one strain of gram positive bacteria is of the genus *Staphylococci*, *Streptococci*, *Enterococci*, *Corynebacteriae*, or *Propionibacterii*.
42. The use of claim 37, wherein the at least one strain of gram positive bacteria is *Staphylococcus epidermis, Staphylococcus cohnii, or Staphylococcus hominis.*
43. The use of claim 37, wherein the *Roseomonas mucosa* is isolated.
44. The use of claim 37, wherein the *Roseomonas mucosa* is present in an amount of from 10^2 to 10^{12} colony forming units.
45. The use of claim 37, wherein *Roseomonas mucosa* is present in an amount sufficient for a reduction in *Staphylococcus aureus* in the subject.
46. The use of claim 37, wherein the at least one strain of *Roseomonas mucosa* comprises a nucleic acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3.