that superantigen antibody titres of > 40 in the IVIG are required for clinical benefit. This is approximately the amount of specific antibody that is found in IVIG and as such multiple doses of IVIG are recommended. The high costs of IVIG, batch to batch variation [8] and difficulties in supply underscore the need for alternative adjunctive therapies.

SUMMARY

Surprisingly, the present inventors have discovered that antibodies or antibody fragments that bind a group A streptococcus M protein fragment or variant thereof with or without antibodies or antibody fragments that bind a group A streptococcus superantigen fragment or variant thereof are surprisingly efficacious against a group A streptococcus-associated disease disorder or condition such as streptococcal toxic shock syndrome.

In one aspect, the present disclosure refers to a use of an antibody or antibody fragment that binds or is raised against a group A streptococcus M protein fragment~~, or a variant or derivative thereof and optionally an antibody or antibody fragment that binds or is raised against a group A streptococcus superantigen protein, fragment, variant or derivative thereof,~~ in the manufacture of a medicament for passively immunizing against, treating or preventing ~~an invasive group A streptococcus disease (iGAS) in a mammal, such as~~ streptococcal toxic shock syndrome (STSS) in a mammal, wherein the M protein fragment is or comprises a conserved region of the M protein.

In another aspect, the present disclosure refers to a use of an antibody or antibody fragment that binds, or is raised against, a group A streptococcus M protein fragment~~, or a variant or derivative thereof,~~ and an antibody or antibody fragment that binds, or is raised against, a ~~group A streptococcus superantigen~~ streptococcal pyrogenic exotoxin (Spe) C protein~~, fragment, variant or derivative thereof~~, in the manufacture of a medicament for passively immunizing against, treating or preventing ~~an invasive group A streptococcus disease (iGAS) in a mammal, such as~~ streptococcal toxic shock syndrome (STSS) in a mammal, wherein the M protein fragment is or comprises a conserved region of the M protein.

In another aspect, the present disclosure refers to a composition formulated for administration to a mammal, said composition comprising: an antibody or antibody fragment that binds, or is raised against, a group A

streptococcus M protein fragment~~, or a variant or derivative thereof~~, wherein the M protein fragment is or comprises a conserved region of the M protein; and an antibody or antibody fragment that binds, or is raised against, a ~~group A streptococcus superantigen~~ streptococcal pyrogenic exotoxin (Spe) C protein~~, fragment, variant or derivative thereof~~

In a broad form, the disclosure therefore relates to use of antibodies or antibody fragments that bind a group A streptococcus M protein, fragment, variant or derivative thereof and optionally an antibody or antibody fragment that binds a group A streptococcus superantigen protein, fragment, variant or derivative thereof to passively immunize against, treat or prevent a group A streptococcus-associated disease disorder or condition such as invasive GAS (iGAS) disease inclusive of streptococcal toxic shock syndrome (STSS).

In another broad form, the disclosure relates to the use of a group A streptococcus M protein fragment, variant or derivative thereof and optionally a group A streptococcus superantigen protein, fragment, variant or derivative thereof to vaccinate or immunize against, treat or prevent a group A streptococcus-associated disease disorder or condition such as invasive GAS (iGAS) disease inclusive of streptococcal toxic shock syndrome (STSS).

An example of the disclosure provides a method of passively immunizing a mammal against streptococcal toxic shock syndrome, said method including the step of administering to the mammal: an antibody or antibody fragment that binds, or is raised against, a group A streptococcus M protein, fragment, variant or derivative thereof, to thereby passively immunize the mammal against streptococcal toxic shock syndrome in the mammal.

CLAIMS

1. Use of an antibody or antibody fragment that binds or is raised against a group A streptococcus M protein fragment~~, or a variant or derivative thereof and optionally an antibody or antibody fragment that binds or is raised against a group A streptococcus superantigen protein, fragment, variant or derivative thereof,~~ in the manufacture of a medicament for passively immunizing against, treating or preventing ~~an invasive group A streptococcus disease (iGAS)~~streptococcal toxic shock syndrome (STSS) in a mammal~~, such as streptococcal toxic shock syndrome (STSS)~~, wherein the M protein fragment is or comprises a conserved region of the M protein.

2. The use of claim 1, wherein the medicament further comprises or is formulated to be administered in combination with an antibody or antibody fragment that binds or is raised against a streptococcal pyrogenic exotoxin (Spe) C protein.

3~~2~~. Use of an antibody or antibody fragment that binds, or is raised against, a group A streptococcus M protein fragment~~, or a variant or derivative thereof~~, and an antibody or antibody fragment that binds, or is raised against, a ~~group A streptococcus~~ streptococcal pyrogenic exotoxin (Spe) C ~~superantigen~~ protein~~, fragment, variant or derivative thereof~~, in the manufacture of a medicament for passively immunizing against, treating or preventing ~~an invasive group A streptococcus disease (iGAS)~~streptococcal toxic shock syndrome (STSS) in a mammal~~, such as streptococcal toxic shock syndrome (STSS)~~, wherein the M protein fragment is or comprises a conserved region of the M protein.

~~3. The use of claim 1 or claim 2, wherein the iGAS is STSS.~~

4. A composition formulated for administration to a mammal, said composition comprising:

an antibody or antibody fragment that binds, or is raised against, a group A streptococcus M protein fragment~~, or a variant or derivative thereof~~, wherein the M protein fragment is or comprises a conserved region of the M protein; and

an antibody or antibody fragment that binds, or is raised against, a ~~group A streptococcus~~ streptococcal pyrogenic exotoxin (Spe) C ~~superantigen~~ protein~~, fragment, variant or derivative thereof~~.

5. The use of any one of claims 1-3, or the composition of claim 4, wherein the M protein fragment is, comprises, or is contained within an amino acid sequence set forth in ~~a p145 peptide~~SEQ ID NO:1.

6. The use of any one of claims 1-3, or the composition of claim 4, wherein the M protein fragment is, comprises, or is contained within an amino acid sequence set forth in ~~a J8 peptide, fragment, variant or derivative thereof~~SEQ ID NO:4.

7. The use of any one of claims 1-3, or the composition of claim 4, wherein the M protein fragment is, comprises, or is contained within an amino acid sequence set forth in ~~a p17 peptide, fragment, variant or derivative thereof~~SEQ ID NO:2 or 6.

8. The use of any one of claims 1-3, or the composition of claim 4, wherein the M protein fragment is, comprises, or is contained within an amino acid sequence selected from the group consisting of SEQ ID NOs:1-10 and 13 to 29.

~~9. The use of any one of claims 1-3 and 5-8, or the composition of any one of claims 4-8, wherein the superantigen is streptococcal pyrogenic exotoxin (Spe) A or SpeC.~~

~~10~~9. The use of any one of claims 1-3 and 5-~~8~~9, or the composition of any one of claims 4-~~8~~9, wherein the antibody or antibody fragment that binds, or is raised against, a group A streptococcus M protein~~,~~ fragment~~, variant or derivative thereof~~ is a monoclonal antibody or antibody fragment.

~~11~~10. The use of any one of claims 2~~1~~-3 and 5-9, or the composition of any one of claims 4-9, wherein the antibody or antibody fragment that binds, or is raised against, ~~a group A streptococcus superantigen~~the SpeC protein~~, fragment, variant or derivative thereof~~ is a monoclonal antibody or antibody fragment.

~~12~~11. The use of claim ~~10~~ 9 or claim ~~11~~10, or the composition of claim ~~10~~ 9 or claim ~~11~~10, wherein the antibody or antibody fragment is a humanized monoclonal antibody or antibody fragment.

~~13~~12. The use of any one of claims 1-3 and 5-11~~12~~, or the composition of any one of claims 4-11~~12~~, wherein the mammal is a human.

13. The use of any one of claims 1-3 and 5-12, or the composition of any one of claims 4-12, wherein the antibody or antibody fragment that binds, or is raised against, a group A streptococcus M protein fragment is a polyclonal antibody or antibody fragment.

14. The use of any one of claims 1-3 and 5-13, or the composition of any one of claims 4-13, wherein the antibody or antibody fragment that binds, or is raised against, the SpeC protein is a polyclonal antibody or antibody fragment.