In one aspect, the present disclosure provides a composition comprising an antibody protein that binds human interleukin-6 receptor, wherein the antibody protein is an anti-IL-6R antibody protein with mannose-5 glycostructure (M5) attached thereto, and wherein the fraction of the anti-IL-6R antibody protein with M5 attached thereto in the composition is 2.7% to 10% of the sum comprising the anti-IL-6R antibody protein with M5, G(0), G(1), and G(2) oligosaccharide attached thereto;

wherein the G(0) glycostructure attached to the anti-IL-6R antibody is in the range from 40 % to 46 % and the G(2) glycostructure attached to the anti-IL- 6R antibody is in the range from 9 % to 11 %;

wherein the anti-IL-6R antibody protein is Tocilizumab;

wherein the anti-IL-6R antibody protein with M5 attached thereto has been produced by a recombinant Chinese Hamster Ovary (CHO) cell; and

wherein the M5 is attached to Asn297 of the anti-IL-6R antibody protein.

In another aspect, the present disclsoure provides a composition comprising Tocilizumab protein with mannose-5 glycostructure (M5) attached to Asn297 thereof, wherein the fraction of Tocilizumab protein with M5 attached thereto in the composition is 2.7% to less than 6 % of the sum comprising Tocilizumab protein with M5, G(0), G(1), and G(2) oligosaccharide attached thereto;

wherein the G(0) glycostructure attached to the Tocilizumab protein is in the range from 40 % to 46 % and the G(2) glycostructure attached to the Tocilizumab protein is in the range from 9 % to 11 %; and

wherein the Tocilizumab protein with M5 attached thereto has been produced by a recombinant Chinese Hamster Ovary (CHO) cell.

Patent Claims

1. A composition comprising an antibody protein that binds human interleukin-6 receptor, wherein the antibody protein is an anti-IL-6R antibody protein with mannose-5 glycostructure (M5) attached thereto, and wherein the fraction of the anti-IL-6R antibody protein with M5 attached thereto in the composition is 2.7% to 10% of the sum comprising the anti-IL-6R antibody protein with M5, G(0), G(1), and G(2) oligosaccharide attached thereto;

   wherein the G(0) glycostructure attached to the anti-IL-6R antibody is in the range from 40 % to 46 % and the G(2) glycostructure attached to the anti-IL-6R antibody is in the range from 9 % to 11 %;

   wherein the anti-IL-6R antibody protein is Tocilizumab;

   wherein the anti-IL-6R antibody protein with M5 attached thereto has been produced by a recombinant Chinese Hamster Ovary (CHO) cell; and

   wherein the M5 is attached to Asn297 of the anti-IL-6R antibody protein.

2. The composition according to claim 1, wherein the M5 fraction is 6% or less.

3. The composition according to claim 1 or 2, further comprising anti-IL-6R antibody protein with G(0), G(1), or G(2) oligosaccharide attached thereto.

4. The composition according to any one of claims 1 to 3, wherein the M5 fraction is in the range from 2.8% to 6%.

5. The composition according to any one of claims 1 to 4, wherein the M5 fraction is 4% or less.

6. A composition comprising Tocilizumab protein with mannose-5 glycostructure (M5) attached to Asn297 thereof, wherein the fraction of Tocilizumab protein with M5 attached thereto in the composition is 2.7% to less than 6 % of the sum comprising Tocilizumab protein with M5, G(0), G(1), and G(2) oligosaccharide attached thereto;

   wherein the G(0) glycostructure attached to the Tocilizumab protein is in the range from 40 % to 46 % and the G(2) glycostructure attached to the Tocilizumab protein is in the range from 9 % to 11 %; and

   wherein the Tocilizumab protein with M5 attached thereto has been produced by a recombinant Chinese Hamster Ovary (CHO) cell.

7. The composition according to claim 6, wherein the M5 fraction is 5% or less.

8. The composition according to claim 6, wherein the M5 fraction is in the range from 2.8% to less than 5%.

9. The composition according to any one of claims 6 to 8, wherein the M5 fraction is 4% or less.

10. The composition according to any one of claims 6 to 9, further comprising the Tocilizumab protein with G(0), G(1), or G(2) oligosaccharide attached to Asn297 thereof.