Claims

1. A composition comprising glycosylated polypeptides characterized in that said glycosylated polypeptide is a polypeptide selected from the group consisting of:

(a) a polypeptide consisting of the amino acid sequence represented by SEQ ID NO. 1;

(b) a polypeptide comprising the amino acid sequence represented by SEQ ID NO. 1, wherein 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 amino acids are different or wherein 20% or less and preferably 10% or less amino acids of the length of the entire amino acid sequence are different;

(c) an interferon β analog; and

(d) a polypeptide having 80% or more homology with a polypeptide consisting of the amino acid sequence represented by SEQ ID NO. 1;

wherein the polypeptide has a sugar chain at the amino acid corresponding to position 80 in interferon β and has interferon β activity,

the glycosylated polypeptides are prepared by chemical synthesis, and

the sugar chains are 90% or more uniform among said glycosylated polypeptides.

2. A composition according to claim 1, characterized in that the glycosylated polypeptides in said composition are 90% or more pure.

3. A pharmaceutical composition characterized in that it comprises:

(I) the glycosylated polypeptides according to claim 1 and/or a pharmaceutically acceptable salt thereof, and

(II) a pharmaceutically acceptable carrier.

4. A pharmaceutical composition according to claim 3, characterized in that sugar chains are 90% or more uniform among said glycosylated polypeptides

5. A pharmaceutical composition according to claim 3 or 4, characterized in that said glycosylated polypeptides are 90% or more pure.

6. A pharmaceutical composition according to any one of claims 3 to 5, for use in treating or preventing an interferon β-related disease.

7. A pharmaceutical composition for use according to claim 6, characterized in that said interferon β-related disease is at least one disease selected from the group consisting of a brain tumor including multi-glioblastoma, medulloblastoma, and astrocytoma, cutaneous malignant melanoma, chronic active hepatitis B, chronic hepatitis C, subacute sclerosing panencephalitis, compensated cirrhosis C, and multiple sclerosis.

8. A glycosylated polypeptide characterized in that said glycosylated polypeptide is a polypeptide selected from the group consisting of:

(a) a polypeptide consisting of the amino acid sequence represented by SEQ ID NO. 1;

(b) a polypeptide comprising the amino acid sequence represented by SEQ ID NO. 1, wherein 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 amino acids are different or wherein 20% or less and preferably 10% or less amino acids of the length of the entire amino acid sequence are different;

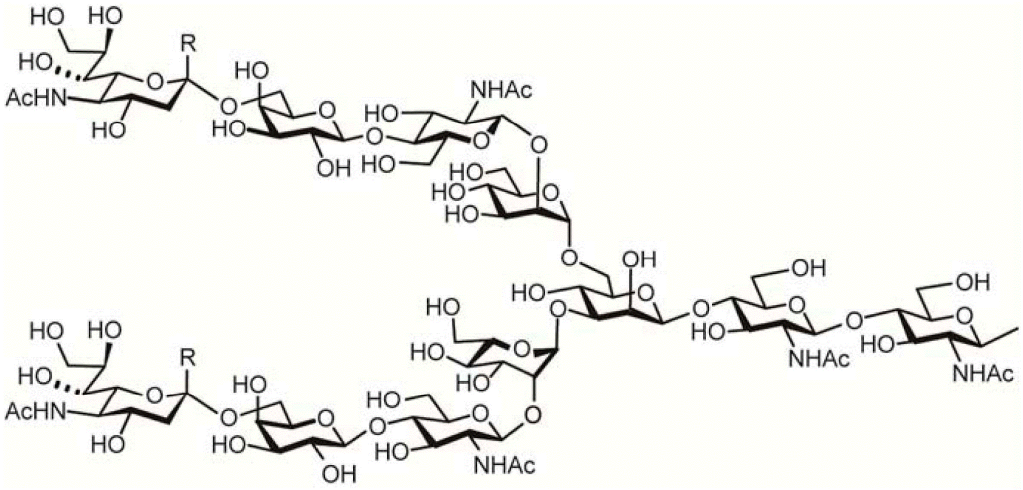
(c) an interferon β analog; and

(d) a polypeptide having 80% or more homology with a polypeptide consisting of the amino acid sequence represented by SEQ ID NO. 1;

wherein the polypeptide has a sugar chain at the amino acid corresponding to position 80 in interferon β and has Cys corresponding to positions 17, 31, and 141 in interferon β protected by a protecting group.

9. A glycosylated polypeptide according to claim 8, characterized in that said sugar chain is a disialo sugar chain represented by the following formula (c) or an asialo sugar chain represented by the following formula (b).

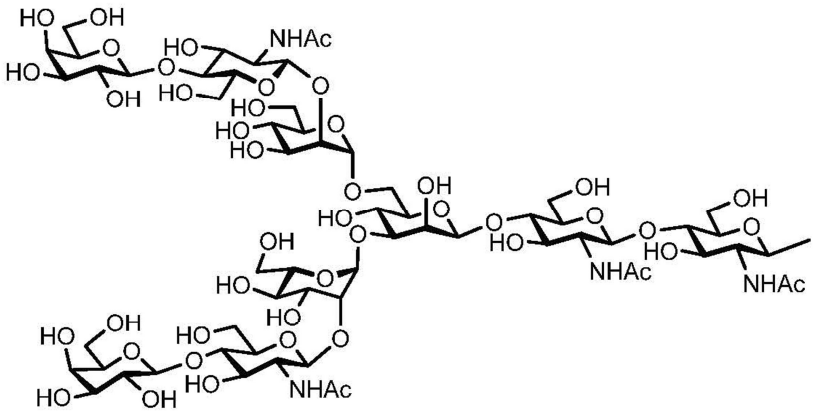
[Chemical Formula 3]



(c)

(wherein R represents -COOBn, -COOEt, -COOMe, -$COOCH_2COPh$, -$COOCH_2PhOMe$, -$COOCH_2Ph(OMe)_2$, -$COOCH_2PhNO_2$, or -$COOCH_2Ph(NO_2)_2$. Bn indicates a benzyl group, Et indicates an ethyl group, Me indicates a methyl group, and Ph indicates a phenyl group).

[Chemical Formula 4]



(b)

10. A glycosylated polypeptide according to claim 8 or 9, characterized in that Cys corresponding to said positions 17, 31, and 141 in interferon β are protected by any one protecting group selected from the group consisting of an Acm group, an alkoxymethyl group, a triphenylmethyl group, a t-butyl group, a benzyl group, and an ethyl group having the β position substituted.

11. A method for manufacturing a glycosylated polypeptide, characterized in that it comprises a step of deprotecting Cys corresponding to said positions 17, 31, and 141 in interferon β protected by a protecting group in the glycosylated polypeptide according to any one of claims 8 to 10.

12. A method for manufacturing a glycosylated polypeptide according to claim 11, characterized in that the glycosylated polypeptide is heat-treated before the step of deprotecting the protecting group of Cys.

13. A glycosylated polypeptide, characterized in that said glycosylated polypeptide is a polypeptide selected from the group consisting of:

(a) a polypeptide consisting of the amino acid sequence represented by SEQ ID NO. 1;

(b) a polypeptide comprising the amino acid sequence represented by SEQ ID NO. 1, wherein 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 amino acids are different or wherein 20% or less and preferably 10% or less amino acids of the length of the entire amino acid sequence are different;

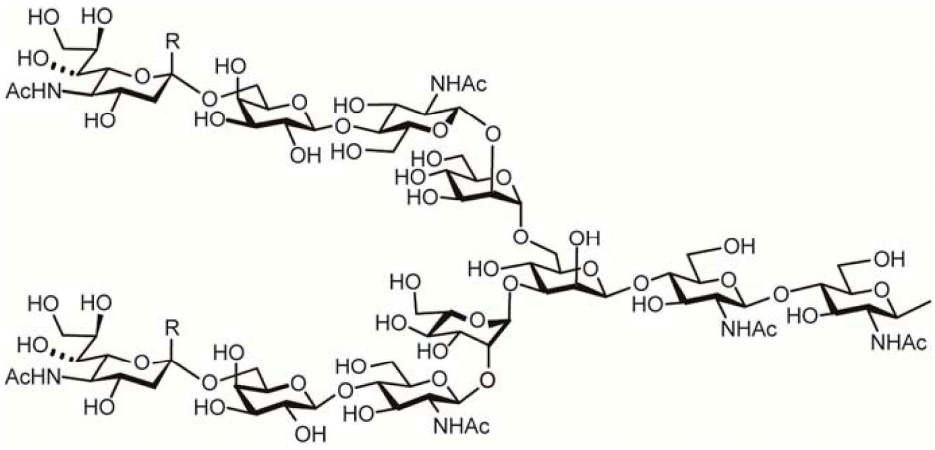
(c) an interferon β analog; and

(d) a glycosylated polypeptide having 80% or more homology with a polypeptide consisting of the amino acid sequence represented by SEQ ID NO. 1;

wherein the polypeptide has a sugar chain at the amino acid corresponding to position 80 in interferon β, and

said sugar chain is a disialo sugar chain wherein the carboxy group of the sialic acid present at the sugar chain non-reducing terminal is protected as represented by the following formula (c).

[Chemical Formula 5]



(c)

(wherein R represents -COOBn, -COOEt, -COOMe, -$COOCH_2COPh$, -$COOCH_2PhOMe$, -$COOCH_2Ph(OMe)_2$, -$COOCH_2PhNO_2$, or -$COOCH_2Ph(NO_2)_2$. Bn indicates a benzyl group, Et indicates an ethyl group, Me indicates a methyl group, and Ph indicates a phenyl group).

14. A method for manufacturing a glycosylated polypeptide, characterized in that it comprises a step of deprotecting the protecting group of the carboxy group of the sialic acid present at the sugar chain non-reducing terminal in the glycosylated polypeptide according to claim 13.

15. A method for manufacturing a glycosylated polypeptide according to any one of claims 11, 13, and 14, characterized in that it further comprises a step of folding said glycosylated polypeptide.