CLAIMS

1. A lyophilized formulation comprising;

a fusion protein including an anti-human transferrin receptor (hTfR) antibody and a human iduronate-2-sulfatase, as an active ingredient, and further

sodium chloride, sucrose, ~~a nonionic surfactant~~ polyoxyethylene(160)polyoxypropylene(30)glycol, and a phosphate buffer,

~~wherein the nonionic surfactant is polysorbate or poloxamer, and~~

wherein the pH is 5.5 to 7.5 when the lyophilized formulation is dissolved in pure water, and

wherein the light chain of the anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:6, and wherein the heavy chain of the anti-hTfR antibody having the amino acid sequence set forth as SEQ ID NO:10 is linked, on the C-terminal side thereof, to the human iduronate-2-sulfatase via a linker.

~~2. The lyophilized formulation according to claim 1, wherein the nonionic surfactant is selected from the group consisting of polysorbate 20, polysorbate 80, and polyoxyethylene(160)polyoxypropylene(30)glycol.~~

~~3. The lyophilized formulation according to claim 1, wherein the nonionic surfactant is polyoxyethylene(160)polyoxypropylene(30)glycol.~~

~~4~~2. The lyophilized formulation according to ~~any one of~~ claim~~s~~ 1 ~~to 3~~, wherein the amounts of sodium chloride, sucrose, and ~~the nonionic surfactant~~ polyoxyethylene(160)polyoxypropylene(30)glycol are 0.015

to 2.5 (w/w), 2.5 to 200 (w/w), and 0.005 to 6 (w/w), respectively, relative to the amount of the fusion protein.

~~5~~3. The lyophilized formulation according to ~~any one of~~ claim~~s~~ 1 ~~to 3~~, wherein the amounts of sodium chloride, sucrose, and ~~the nonionic surfactant~~ polyoxyethylene(160)polyoxypropylene(30)glycol are 0.05 to 0.5 (w/w), 5 to 50 (w/w), and 0.02 to 0.2 (w/w), respectively, relative to the amount of the fusion protein.

~~6~~4. The lyophilized formulation according to ~~any one of~~ claim~~s~~ 1 ~~to~~

~~3~~, wherein the amounts of sodium chloride, sucrose, and ~~the nonionic surfactant~~ polyoxyethylene(160)polyoxypropylene(30)glycol is 0.1 to 0.25 (w/w), 10 to 25 (w/w), and 0.04 to 0.1 (w/w), respectively, relative to the amount of the fusion protein.

~~7. The lyophilized formulation according to any one of claims 1 to 6, wherein the fusion protein is a fusion protein in which the human iduronate-2-sulfatase is linked to the light chain or the heavy chain of the antibody on the C-terminal side thereof by a peptide bond.~~

~~8. The lyophilized formulation according to any one of claims 1 to 6, wherein the fusion protein is a fusion protein in which the human iduronate-2-sulfatase is linked to the heavy chain of the antibody on the C-terminal side thereof by a peptide bond.~~

~~9. The lyophilized formulation according to any one of claims 1 to 6, wherein the fusion protein is a fusion protein in which the human iduronate-2-sulfatase is linked to the light chain or the heavy chain of the antibody on the C-terminal side thereof via a linker including one or more of amino acids.~~

~~10. The lyophilized formulation according to any one of claims 1 to 6, wherein the fusion protein is a fusion protein in which the human iduronate-2-sulfatase is linked to the heavy chain of the antibody on the C-terminal side thereof via a linker including one or more of amino acids.~~

~~11~~5. The lyophilized formulation according to ~~claim 9 or 10~~any one of claims 1 to 4, wherein the linker includes the amino acid sequence of Gly-Ser.

~~12. The lyophilized formulation according to any one of claims 1 to~~

~~11, wherein the antibody is a human antibody or a humanized antibody.~~

~~13. The lyophilized formulation according to claim 12, wherein the antibody is a humanized anti-human transferrin receptor (hTfR) antibody.~~

~~14. The lyophilized formulation according to claim 12, wherein the antibody is a humanized anti-hTfR antibody, and wherein the fusion protein is selected from the group consisting of (a) to (c) below;~~

~~(a) the fusion protein, wherein the light chain of the humanized anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:2, and wherein the heavy chain of the humanized anti-hTfR antibody having the amino acid sequence set forth as SEQ ID NO:8 is linked, on the C-terminal side thereof, to the human iduronate-2-sulfatase via a linker sequence,~~

~~(b) the fusion protein, wherein the light chain of the humanized anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:4, and wherein the heavy chain of the humanized anti-hTfR antibody having the amino acid sequence set forth as SEQ ID NO:9 is linked, on the C-terminal side thereof, to the human iduronate-2-sulfatase via a linker sequence,~~

~~(c) the fusion protein, wherein the light chain of the humanized anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:6, and wherein the heavy chain of the humanized anti-hTfR antibody having the amino acid sequence set forth as SEQ ID NO:10 is linked, on the C-terminal side thereof, to the human iduronate-2-sulfatase via a linker sequence.~~

~~15~~6. The lyophilized formulation according to ~~claim 12~~ any one of claims 1 to 5, ~~wherein the antibody is a humanized anti-hTfR antibody,~~

~~and wherein the fusion~~

~~protein is selected from the group consisting of (a) to (c) below;~~

~~(a) the fusion protein, wherein the light chain of the humanized anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:2, and wherein the heavy chain of the humanized anti-hTfR antibody is linked, on the C-terminal side thereof and via a linker sequence of Gly-Ser, to the human iduronate-2-sulfatase, and the whole linked heavy chain has the amino acid sequence set forth as SEQ ID NO:13,~~

~~(b) the fusion protein, wherein the light chain of the humanized anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:4, and wherein the heavy chain of the humanized anti-hTfR antibody is linked, on the C-terminal side thereof and via a linker sequence of Gly-Ser, to the human iduronate-2-sulfatase, and the whole linked heavy chain has the amino acid sequence set forth as SEQ ID NO:15, and~~

~~(c) the fusion protein,~~ wherein the light chain of the ~~humanized~~ anti-hTfR antibody has the amino acid sequence set forth as SEQ ID NO:6, and wherein the heavy chain of the ~~humanized~~ anti-hTfR antibody is linked, on the C-terminal side thereof and via a linker sequence of Gly-Ser, to the human iduronate-2-sulfatase, and the whole linked heavy chain has the amino acid sequence set forth as SEQ ID NO:17.

~~16~~7. The lyophilized formulation according to any one of claims 1 to ~~15~~6, sealed in a container formed of a borosilicate glass or a hydrophobic resin.

~~17~~8. The lyophilized formulation according to claim ~~16~~7, wherein the

container is formed by a cycloolefin copolymer, a ring-opened polymer of cycloolefin, or a hydrogenated ring-opened polymer of cycloolefin.