~~What is claimed is:~~

CLAIMS

~~1.~~ 1. A composition comprising a recombinant human acid sphingomyelinase~~, sodium phosphate, methionine, and sucrose.~~

~~2.~~ ~~The composition of claim 1~~, wherein the composition is a lyophilized composition comprising:

4-7% w/w olipudase alfa (SEQ ID NO:2),

3-7% w/w sodium phosphate,

15-25% w/w L-methionine, and

65-75% w/w sucrose.

~~3.~~ 2. The composition of claim ~~2~~1, consisting essentially of:

5.5% w/w olipudase alfa,

2.3% w/w sodium phosphate dibasic heptahydrate,

2.6% w/w sodium phosphate monobasic monohydrate,

20.5% w/w L-methionine, and

68.6% w/w sucrose.

~~4.~~ ~~The~~3. A composition ~~of claim 1~~comprising a recombinant human acid sphingomyelinase, wherein the composition is an aqueous liquid composition comprising:

1-10 mg/mL olipudase alfa,

10-50 mM sodium phosphate,

70-150 mM L-methionine, and

1-10% w/v sucrose,

wherein the composition has a pH of 5-8.

~~5.~~ 4. The composition of claim ~~4~~3, wherein the composition is an aqueous liquid composition comprising:

3-5 mg/mL olipudase alfa,

10-30 mM sodium phosphate,

80-120 mM L-methionine, and

4-6% w/v sucrose,

wherein the composition has a pH of 6-7.

~~6.~~ 5. The composition of claim ~~4~~3, consisting essentially of:

4 mg/mL olipudase alfa,

20 mM sodium phosphate,

100 mM L-methionine, and

5% w/v sucrose,

wherein the composition has a pH of 6.5.

~~7.~~ 6. The composition of any one of claims ~~4-6~~3-5, further comprising 0.005% w/v polysorbate 80.

~~8.~~ 7. A composition obtained by lyophilizing the aqueous liquid composition of any one of claims ~~4-7~~3-6.

~~9.~~ 8. A process for manufacturing a lyophilized composition, comprising:

obtaining the aqueous liquid composition of any one of claims ~~4-7~~3-6, and

lyophilizing the aqueous liquid composition.

~~10.~~ 9. A vial containing a lyophilized composition consisting essentially of:

21.2 mg olipudase alfa,

9.0 mg sodium phosphate dibasic heptahydrate,

10.0 mg sodium phosphate monobasic monohydrate,

79 mg L-methionine, and

265 mg sucrose.

~~11.~~ 10. An aqueous liquid composition obtained by reconstituting a lyophilized composition consisting essentially of:

21.2 mg olipudase alfa,

9.0 mg sodium phosphate dibasic heptahydrate,

10.0 mg sodium phosphate monobasic monohydrate,

79 mg L-methionine, and

265 mg sucrose,

in 5.1 mL of sterile water.

~~12.~~ 11. A vial containing a lyophilized composition consisting essentially of:

4.8 mg olipudase alfa,

2.0 mg sodium phosphate dibasic heptahydrate,

2.3 mg sodium phosphate monobasic monohydrate,

17.9 mg L-methionine, and

60 mg sucrose.

~~13.~~ 12. An aqueous liquid composition obtained by reconstituting a lyophilized composition consisting essentially of:

4.8 mg olipudase alfa,

2.0 mg sodium phosphate dibasic heptahydrate,

2.3 mg sodium phosphate monobasic monohydrate,

17.9 mg L-methionine, and

60 mg sucrose

in 1.1 mL of sterile water.

13. The composition of claim 1, 2 or 7, or the vial of claim 9 or 11, wherein the lyophilized composition comprises 0.1%, 0.2%, 0.3%, 0.4%, or 0.5% moisture.

~~14.~~ 14. An article of manufacture comprising the vial of claim ~~10~~9 or ~~12~~11 and a vial containing sterile water, 0.9% sodium chloride, or phosphate-buffered saline for reconstituting the lyophilized composition.

~~A method of treating acid sphingomyelinase deficiency (ASMD) in a human patient, comprising administering to the patient the~~

~~15.~~ 15. A composition of any one of claims 1-~~8, 11, and 13, wherein the composition is reconstituted into a liquid form prior to administration if it is a lyophilized composition.~~

~~16.~~ ~~A composition of any one of claims 1-8, 11,~~7, 10, 12 and 13 for use in treating ASMD in a human patient.

~~17.~~ 16. Use of a composition of any one of claims 1-~~8, 11,~~7, 10, 12 and 13 for the manufacture of a medicament for treating ASMD in a human patient.

~~18.~~ 17. The ~~method of claim 15, the~~ composition for use of claim ~~16~~15, or the use of claim ~~17~~16, wherein the ASMD is Niemann-Pick Disease type A/B or type B.

~~19.~~ 18. The ~~method,~~ composition for use~~,~~ or use of ~~claim 18~~any one of claims 15-17, wherein the treatment is for non-neurological manifestations of ASMD.