CLAIMS

1. Use of a hyaluronidase PH20 enzyme formulation formulated for subcutaneous administration in the manufacture of a medicament for the treatment of a disease or disorder in a subject in need thereof, wherein the formulation comprises recombinant human hyaluronidase PH20 enzyme comprising a sequence having at least 95% amino acid sequence identity to an amino acid sequence selected from any of SEQ ID NO: 1 through 7 or 15, and having an activity of 500 U/mL to 5,000 U/mL, and an active ingredient selected from a small molecule, a peptide fragment, a biologic, a nanoparticle, an antibody, an antibody fragment, and a small molecule antiviral; wherein the formulation is to be administered via subcutaneous administration at a volume of 3 mL to 50 mL and the subcutaneous administration is facilitated by a prefilled autoinjection or autoinfusion device comprising:

a delivery apparatus comprising:

a housing having a proximal end and a distal end opposite the proximal end;

a medicament container at least partially disposed within the housing containing a volume of a medicament;

an outlet on the distal end of the housing in fluid communication with the medicament container;

an energy source disposed within the housing configured to interact with the medicament container to expel the medicament from the outlet; and

a trigger mechanism coupled to the housing and engageable with the energy source and configured to activate the energy source in response to a user input;

a port having a user engagement surface, and an injection apparatus extending from the user engagement surface; and

a conduit removably coupled to the outlet and the port and fluidly connecting the delivery apparatus and the port when coupled therebetween.

2. Use of a hyaluronidase PH20 enzyme formulation formulated for subcutaneous administration in the manufacture of a medicament for the treatment of a disease or disorder in a subject in need thereof, wherein the formulation comprises recombinant human hyaluronidase PH20 enzyme comprising a sequence having at least 95% amino acid sequence identity to an amino acid sequence selected from any of SEQ ID NO: 1 through 7 or 15, and having an activity of 500 U/mL

to 5,000 U/mL, and an active ingredient selected from a small molecule, a peptide fragment, a biologic, a nanoparticle, an antibody, an antibody fragment, and a small molecule antiviral; wherein the subcutaneous administration is facilitated by a prefilled autoinjection or autoinfusion device comprising:

a delivery apparatus comprising:

a housing having a proximal end and a distal end opposite the proximal end;

a medicament container at least partially disposed within the housing containing a volume of at least 10 mL of a medicament;

an outlet on the distal end of the housing in fluid communication with the medicament container;

an energy source disposed within the housing configured to interact with the medicament container to expel the medicament from the outlet; and

a trigger mechanism coupled to the housing and engageable with the energy source and configured to activate the energy source in response to a user input;

a port comprising:

a user engagement surface; and

a needle extending from the user engagement surface; and

a flexible tube removably coupled to the outlet and the port and fluidly connecting the delivery apparatus and the port when coupled therebetween,

wherein the delivery apparatus is not resettable.

3. Use of a hyaluronidase PH20 enzyme formulation formulated for subcutaneous administration in the manufacture of a medicament for delivering a formulation to a subject in need thereof, wherein the formulation comprises recombinant human hyaluronidase PH20 enzyme comprising a sequence having at least 95% amino acid sequence identity to an amino acid sequence selected from any of SEQ ID NO: 1 through 7 or 15, and having an activity of 500 U/mL to 5,000 U/mL, and an active ingredient selected from a small molecule, a peptide fragment, a biologic, a nanoparticle, an antibody, an antibody fragment, and a small molecule antiviral, wherein the formulation is to be administered via subcutaneous administration at a volume of 3 mL to 50 mL into a patient with a delivery apparatus comprising a prefilled medicament container containing a volume of the formulation, an energy source configured to interact with the medicament container to expel the formulation and a trigger mechanism configured to activate the energy source in response to a user input, wherein:

the delivery apparatus is coupled to a first end of a conduit, the conduit in fluid communication with the prefilled medicament container;

a second end of the conduit is coupled to a port comprising an injection apparatus extending therefrom, the injection apparatus in fluid communication with the prefilled medicament container;

the injection apparatus is configured for insertion into an injection site on a patient; and

the trigger mechanism is configured for manipulation to allow the energy source to expel the formulation from the prefilled medicament container;

a port having a user engagement surface, and an injection apparatus extending from the user engagement surface; and

a conduit removably coupled to the outlet and the port and fluidly connecting the delivery apparatus and the port when coupled therebetween;

wherein the energy source urges the volume of the formulation through the injection apparatus during the injection.

4. The use according to any one of claims 1-3, wherein the delivery apparatus is configured to purge the conduit of air before the injection apparatus is inserted into an injection site of a patient.

5. The use according to any one of claims 1-3, wherein the delivery apparatus is configured to purge the conduit of air after the injection apparatus is inserted into an injection site of a patient.

6. The use according to any one of claims 1-3, wherein the delivery apparatus is configured to automatically purge the conduit of air when the conduit is coupled to the delivery apparatus.

7. The use according to any one of claims 1-3, wherein the conduit is decoupled from the port after the volume of the medicament is expelled from the outlet.

8. The use according to any one of claims 1-3, wherein the conduit is a flexible tubing.

9. The use according to any one of claims 1-3, wherein the conduit is at least 24 inches in length.

10. The use according to any one of claims 1-3, wherein the energy source is prevented from expelling medicament from the outlet until the conduit is purged of air.

11. The use according to any one of claims 1-3, wherein the delivery apparatus is not resettable.

12. The use according to any one of claims 1-3, wherein the outlet is a generally cylindrical member and comprises threads protruding therefrom.

13. The use according to any one of claims 1-12, wherein the active ingredient is a small molecule, a peptide fragment, a biologic, or a nanoparticle.

14. The use according to any one of claims 1-12, wherein the active ingredient is an antibody, an antibody fragment, or a small molecule antiviral.

15. The use according to any one of claims 1-14, wherein the formulation is 10 mL to 20 mL.

16. The use according to any one of claims 1-14, wherein the formulation is 3 mL to 15 mL.

17. The use according to any one of claims 1-16, wherein the prefilled autoinjection or autoinfusion device is configured to administer the formulation with one or more of (i) to (iv):

(i) a starting delivery force of 5 lbf to 50 lbf;

(ii) an ending delivery force of 3 lbf to 20 lbf;

(iii) a starting pressure of 50 psi to 200 psi; and

(iv) an ending pressure of 20 psi to 75 psi.

18. The use according to any one of claims 1-17, wherein the medicament container is a prefilled syringe.

19. The use according to claim 18, wherein the prefilled syringe comprises a needle having a gauge of 20 to 33.

20. The use according to any one of claims 1-19, wherein the prefilled autoinjection or autoinfusion device is configured to administer the formulation at a rate of 5 mL/min to 20 mL/min.

21. The use according to any one of claims 1-20, wherein the subcutaneous administration takes 30 seconds to 360 seconds.

22. The use according to any one of claims 1-21, wherein the subcutaneous administration takes 60 seconds to 240 seconds.

23. The use according to any one of claims 1-22, wherein the formulation has a viscosity of 1 cP to 50 cP.

24. The use according to any one of claims 1-23, wherein one or more of (i) to (x) is true:

(i) administration of the formulation requires less applied force when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

(ii) administration of the formulation is faster when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

(iii) administration of the formulation causes fewer side effects in the subject when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

(iv) administration of the formulation causes less pain and discomfort in the subject when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

(v) administration of the formulation causes less back leakage at the injection site when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

(vi) the back leakage at the injection site is 100% to 30% less when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

(vii) administration of the formulation causes less swelling volume and/or swelling height at the injection site when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

(viii) administration of the formulation causes 35% to 1% less swelling and/or swelling height the injection site when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

(ix) administration of the formulation yields a lower bleb swelling size, less bleb induration, and/or quicker bleb resolution when compared to a similar formulation that does not comprise a hyaluronidase enzyme; and

(x) administration of the formulation yields more consistent delivery times when compared to a similar formulation that does not comprise a hyaluronidase enzyme.

25. The use according to any one of claims 1-24, wherein the subject is human.

26. The use according to any one of claims 1-25, wherein the prefilled autoinjection or autoinfusion device is configured for self-administration.

27. The use according to any one of claims 1-26, wherein the subcutaneous administration comprises a single injection.

28. The use according to any one of claims 1-27, wherein the subcutaneous administration comprises two or more injections.