CLAIMS

1. An inhalable dry powder formulation comprising:

a recombinant alpha-1-antitrypsin protein;

a force control agent comprising di-leucine and tri-leucine in combination thereof, wherein the force control agent is present in an amount of at least 50% by weight of the formulation; and

pharmaceutically acceptable excipients including a sodium salt and a non-reducing sugar or a sugar alcohol or a combination thereof.

2. The inhalable dry powder formulation according to claim 1, wherein the formulation is in crystalline form.

3. The inhalable dry powder formulation according to claim 1, wherein the di-leucine and the tri-leucine in the force control agent are present in a ratio ranging from 49:1 to 90:1, 9:1, 4:1, 7:3, 3:2 or 1:1.

4. The inhalable dry powder formulation according to claim 3, wherein the di-leucine and the tri-leucine in the force control agent are present in a ratio of 4:1.

5. The inhalable dry powder formulation according to any one of the preceding claims, wherein the formulation has a moisture content of less than 1% by weight based on the total weight of the formulation.

6. The inhalable dry powder formulation according to claim 1, wherein the inhalable dry powder formulation has an increased bioactivity of up to 19% as compared to a pre-formulated recombinant alpha-1-antitrypsin protein.

7. An inhalable dry powder formulation for use in the treatment of genetic and autoimmune disorders associated with alpha-1-antitrypsin deficiency, the formulation comprising:

a recombinant alpha-1-antitrypsin protein;

a force control agent comprising di-leucine and tri-leucine in combination thereof, wherein the force control agent is present in an amount of at least 50% by weight of the formulation; and

pharmaceutically acceptable excipients including a sodium salt and a non-reducing sugar or a sugar alcohol or a combination thereof.

8. The inhalable dry powder formulation according to claim 7, wherein the formulation is in crystalline form.

9. The inhalable dry powder formulation according to any one of claims 7 to 8, wherein the di-leucine and the tri-leucine in the force control agent are present in a ratio ranging from 49:1 to 90:1, 9:1, 4:1, 7:3, 3:2 or 1:1.

10. The inhalable dry powder formulation according to claim 9, wherein the di-leucine and the tri-leucine in the force control agent are present in a ratio of 4:1.

11. The inhalable dry powder formulation according to any one of claims 7 to 10, wherein the formulation has a moisture content of less than 1% by weight based on the total weight of the formulation.

12. Use of an inhalable dry powder formulation comprising:

a recombinant alpha-1-antitrypsin protein;

a force control agent comprising di-leucine and tri-leucine in combination thereof, wherein the force control agent is present in an amount of at least 50% by weight of the formulation, and

pharmaceutically acceptable excipients including a sodium salt and a non-reducing sugar or a sugar alcohol or a combination thereof, in the manufacture of a pharmaceutical composition for treating genetic and autoimmune disorders associated with alpha-1-antitrypsin deficiency in a subject.

13. The use according to claim 12, wherein the formulation is in crystalline form.

14. The use according to any one of claims 12 to 13, wherein the di-leucine and the tri-leucine in the force control agent are present in a ratio ranging from 49:1 to 90:1, 9:1, 4:1, 7:3, 3:2 or 1:1.

15. The use according to claim 14, wherein the di-leucine and the tri-leucine in the force control agent are present in a ratio of 4:1.

16. The use according to any one of claims 12 to 15, wherein the formulation has a moisture content of less than 1% by weight based on the total weight of the formulation.

17. A delivery system comprising an inhaler device and an inhalable dry powder formulation as defined in claim 1.