**WHAT IS CLAIMED IS:**

1. A HDL Therapeutic for use in a method of identifying a dose of the HDL Therapeutic effective to mobilize cholesterol in a subject, the method comprising:

(a) administering a first dose of the HDL Therapeutic to a subject,

(b) following administering said first dose, measuring expression levels of one or more HDL Markers in said subject's circulating monocytes, macrophages or mononuclear cells to evaluate the effect of said first dose on said expression levels; and

(c) (i) if the subject's expression levels of one or more HDL Markers are reduced by more than a cutoff amount, administering a second dose of said HDL Therapeutic, wherein the second dose of said HDL Therapeutic is lower than the first dose; or

(ii) if the subject's expression levels of one or more HDL Markers are not reduced by more than the cutoff amount, treating the subject with the first dose of said HDL Therapeutic.

2. The HDL Therapeutic for use according to claim 1, wherein the cutoff amount is (i) relative to the subject's own baseline prior to said administration or (ii) relative to a control amount, which is optionally a population average, which is optionally from healthy subjects or from a population with the same disease condition as the subject.

3. The HDL Therapeutic for use according to claim 1 or 2 which further comprises determining a cutoff amount, optionally wherein the cutoff amount is determined by generating a dose response curve for the HDL Therapeutic, and optionally wherein the cutoff amount is 25% - 75% or 40%-60% of the dose that results in an inflection point in the dose response curve.

4. The HDL Therapeutic for use according to claim 1 or claim 2, wherein the method further comprises, following administering said second dose, measuring expression levels of one or more HDL Markers in said subject's circulating monocytes, macrophages or mononuclear cells to evaluate the effect of said second dose on said expression levels, and optionally wherein if the subject's expression levels of one or

more HDL Markers are reduced by more than a cutoff amount, a third dose of said HDL Therapeutic is administered, wherein the third dose of said HDL Therapeutic is lower than the second dose.

5. The HDL Therapeutic for use according to any one of claims 1 to 4, wherein

(a) at least one HDL Marker is ABCA1, optionally wherein ABCA1 mRNA expression levels or ABCA1 protein expression levels are measured, optionally wherein the ABCA1 cutoff amount is 20%-80%, 30%-70%, 40%-60%, or 50%, and optionally wherein ABCA1 expression levels are measured 2-12 hours, 4-10 hours, 2-8 hours, 2-6 hours, 4-6 hours or 4-8 hours after administration of the HDL Therapeutic;

(b) at least one HDL Marker is ABCG1, optionally wherein ABCG1 mRNA expression levels or ABCG1 protein expression levels are measured, optionally wherein the ABCG1 cutoff amount is 20%-80%, 30%-70%, 40%-60%, or 50%, and optionally wherein ABCG1 expression levels are measured 2-12 hours, 4-10 hours, 2-8 hours, 2-6 hours, 4-6 hours or 4-8 hours after administration of the HDL Therapeutic;

(c) at least one HDL Marker is SREBP-1, optionally wherein SREBP-1 mRNA expression levels or SREBP-1 protein expression levels are measured, optionally wherein the SREBP-1 cutoff amount is 20%-80%, 30%-70%, 40%-60%, or 50%, and optionally wherein SREBP-1 expression levels are measured 2-12 hours, 4-10 hours, 2-8 hours, 2-6 hours, 4-6 hours or 4-8 hours after administration of the HDL Therapeutic; or

(d) any combination of (a)-(c).

6. A HDL Therapeutic for use in a method for monitoring the efficacy of the HDL Therapeutic in a subject, the method comprising:

(a) treating a subject with the HDL Therapeutic according to a first dosing schedule,

(b) measuring expression levels of one or more HDL Markers in said subject's circulating monocytes, macrophages or mononuclear cells to evaluate the effect of said first dosing schedule on said expression levels; and

(c) (i) if the subject's expression levels of one or more HDL Markers are reduced by more than an upper cutoff amount, treating the subject with the HDL Therapeutic according to a second dosing schedule, wherein the second dosing schedule comprises one or more of: administering a lower dose of the HDL Therapeutic, infusing the HDL Therapeutic into the subject over a longer period of time, and administering the HDL Therapeutic to the subject on a less frequent basis;

(ii) if the subject's expression levels of one or more HDL Markers are not reduced by more than a lower cutoff amount, treating the subject with the HDL Therapeutic according to a second dosing schedule, wherein the second dosing schedule comprises one or more of: administering a higher dose of the HDL Therapeutic, infusing the HDL Therapeutic into the subject over a shorter period of time, and administering the HDL Therapeutic to the subject on a more frequent basis; or

(iii) if the subject's expression levels of one or more HDL Markers are reduced by an amount between the upper and lower cutoff amounts, continuing to treat the subject according to the first dosing schedule.

7. The HDL Therapeutic for use according to claim 6, wherein

(a) at least one HDL Marker is ABCA1, optionally wherein ABCA1 mRNA expression levels or ABCA1 protein expression levels are measured, , and optionally wherein ABCA1 expression levels are measured 2-12 hours, 4-10 hours, 2-8 hours, 2-6 hours, 4-6 hours or 4-8 hours after administration of the HDL Therapeutic;

(b) at least one HDL Marker is ABCG1, optionally wherein ABCG1 mRNA expression levels or ABCG1 protein expression levels are measured, and optionally wherein ABCG1 expression levels are measured 2-12 hours, 4-10 hours, 2-8 hours, 2-6 hours, 4-6 hours or 4-8 hours after administration of the HDL Therapeutic;

(c) at least one HDL Marker is SREBP-1, optionally wherein SREBP-1 mRNA expression levels or SREBP-1 protein expression levels are measured, and optionally wherein SREBP-1 expression levels are measured 2-12

hours, 4-10 hours, 2-8 hours, 2-6 hours, 4-6 hours or 4-8 hours after administration of the HDL Therapeutic; or

(d) any combination of (a)-(c).

8. The HDL Therapeutic for use according to any one of claims 1 to 7, wherein the subject is human or a non-human animal, optionally wherein the non-human animal is a mouse.

9. *The HDL Therapeutic for use according to any one of claims 1 to 8, wherein the* subject has an ABCA1 deficiency, optionally wherein the subject is homozygous for an ABCA1 mutation or is heterozygous for an ABCA1 mutation.

10. The HDL Therapeutic for use according to any one of claims 1 to 9, wherein the HDL Therapeutic is

(a) a lipoprotein complex, optionally wherein lipoprotein complex:

(i) comprises an apolipoprotein, which is optionally ApoA-I, ApoA-II, ApoA-IV, ApoE or a combination thereof;

(ii) comprises an apolipoprotein peptide mimic, which is optionally an ApoA-I, ApoA-II, ApoA-IV, or ApoE peptide mimic or a combination thereof; or

(iii) is CER-001, CSL-111, CSL-112, or ETC-216;

or

(b) a small molecule, optionally wherein the small molecule:

(i) is a CETP inhibitor; or

(ii) is a pantothenic acid derivative.

11. A HDL Therapeutic, which is optionally CER-001, for use in a method for treating a subject with an ABCA1 deficiency, optionally wherein the subject is heterozygous for an ABCA1 mutation or homozygous for an ABCA1 mutation.

12. A HDL Therapeutic, which is optionally CER-001, for use in a method of treating a subject suffering from familial primary hypoalphalipoproteinemia, the method comprising:

(a) administering to the subject the HDL Therapeutic according to an induction regimen; and, subsequently

(b) administering to the subject the HDL Therapeutic according to a maintenance regimen, optionally wherein the maintenance regimen entails administering the HDL therapeutic at a lower dose, a lower frequency, or both.

13. The HDL Therapeutic for use according to claim 12, wherein the subject is:

(a) heterozygous or homozygous for an ABCA1 mutation;

(b) homozygous or heterozygous for an LCAT mutation;

(c) homozygous or heterozygous for an ApoA-I mutation;

(d) homozygous or heterozygous for an ABCG1 mutation;

(e) also treated with a lipid control medication, which is optionally is atorvastatin, ezetimibe, niacin, rosuvastatin, simvastatin, aspirin, fluvastatin, lovastatin, pravastatin or a combination thereof; or

(f) any combination of (a)-(e).

14. The HDL Therapeutic for use of claim 1, wherein the HDL Therapeutic comprises CER-001 and optionally wherein:

(a) the induction regimen is of a duration of 4 weeks;

(b) the induction regimen comprises administering CER-001 three times a week;

(c) the dose administered in the induction regimen is 8-15 mg/kg (on a protein weight basis), which is optionally 8 mg/kg, 12 mg/kg or 15 mg/kg;

(d) the maintenance regimen comprises administering CER-001 for at least one month, at least two months, at least three months, at least six months, at least a year, at least 18 months, at least two years, or indefinitely;

(e) the maintenance regimen comprises administering CER-001 twice a week;

(f) the dose administered in the maintenance regimen is 1-6 mg/kg (on a protein weight basis), which is optionally 1 mg/kg, 3 mg/kg or 6 mg/kg.

15. The HDL Therapeutic for use according to any one of claims 12 to 14, wherein:

(a) the induction regimen utilizes a dose that reduces expression levels of one or more HDL Markers by 20%-80% or 40%-60%, as compared to the subject's baseline amount and/or a population average; and/or

(b) the maintenance regimen utilizes a dose that does not reduce expression levels of one or more HDL Markers by more than 20% or more than 10% as compared to the subject's baseline amount and/or a population average, optionally wherein the maintenance regimen utilizes a dose that does not reduce expression levels of one or more HDL Markers.