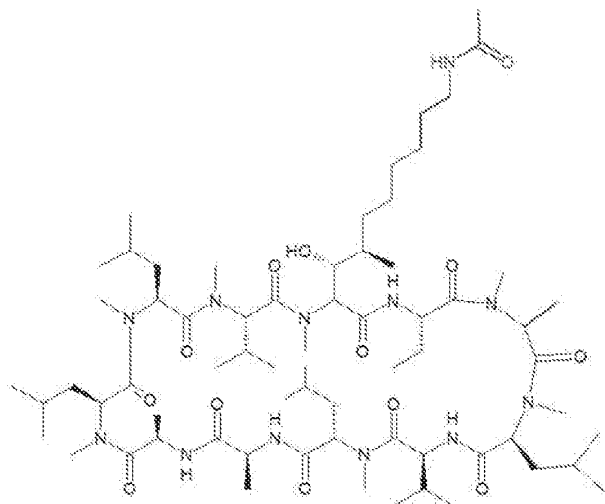


CLAIMS

What is claimed is:

1. A self-microemulsifying drug delivery system (SMEDDS) comprising CRV431:

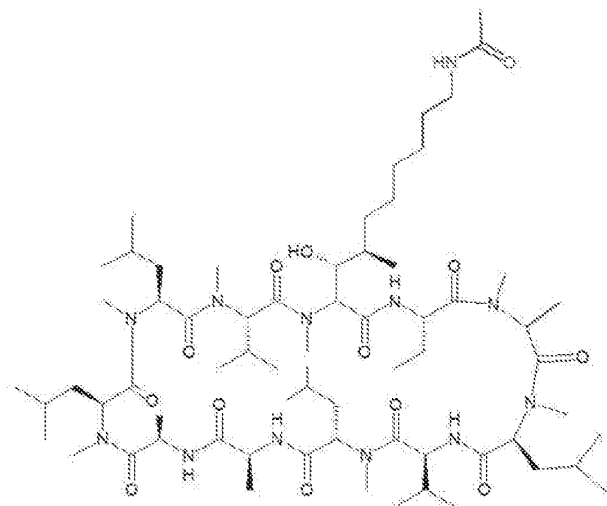


(CRV431),

or a pharmaceutically acceptable salt thereof.

2. The self-microemulsifying drug delivery system of claim 1, wherein the system comprises Cremophor® RH40.
3. The self-microemulsifying drug delivery system of any of the above claims, wherein the system comprises ethanol.
4. The self-microemulsifying drug delivery system of any of the above claims, wherein the system comprises Transcutol®.
5. The self-microemulsifying drug delivery system of any of the above claims, wherein the system comprises propylene glycol.
6. The self-microemulsifying drug delivery system of any of the above claims, wherein the system comprises Maisine® CC.
7. The self-microemulsifying drug delivery system of any of the above claims, wherein the system comprises Vitamin E.
8. The self-microemulsifying drug delivery system of any of the above claims, wherein the system comprises Vitamin E, Maisine® CC, propylene glycol, Transcutol®, ethanol, and Cremophor® RH40 at a weight ratio of 1/1/5/5/2.4/4 or 1/1.5/2.5/5/2.4/5.
9. The self-microemulsifying drug delivery system of any of the above claims, wherein the system comprises CRV431 at a concentration from about 10 mg/mL to about 90 mg/mL.

10. The self-microemulsifying drug delivery system of any of the above claims, wherein the system comprises CRV431 at a concentration of about 90 mg/mL.
11. A pharmaceutical composition comprising:
 - (a) CRV431 at a concentration of from about 10 mg/mL to about 90 mg/mL;



(CRV431);

- (b) Vitamin E;
 - (c) Maisine® CC;
 - (d) propylene glycol;
 - (e) Transcutol®;
 - (f) ethanol; and
 - (g) Cremophor® RH40, wherein Vitamin E, Maisine® CC, propylene glycol, Transcutol®, ethanol, and Cremophor® RH40 are at a weight ratio, respectively, of about (0.75-1.5)/(0.5-2)/(2-5)/(2-5)/(2-2.4)/(4-8).
12. A method of treating a disease in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a self-microemulsifying drug delivery system (SMEDDS) of any one of claims 1-10 or a therapeutically effective amount of a pharmaceutical composition of claim 11.
 13. A method of preventing a disease in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a self-microemulsifying drug delivery system (SMEDDS) of any one of claims 1-10 or a therapeutically effective amount of a pharmaceutical composition of claim 11.
 14. A self-microemulsifying drug delivery system (SMEDDS) of any of claims 1-10, or a pharmaceutical composition of claim 11, for the treatment or prevention of a disease

in a subject.

15. Use of a therapeutically effective amount of a self-microemulsifying drug delivery system (SMEDDS) of any of claims 1-10, or a pharmaceutical composition of claim 11, in the manufacture of a medicament for the treatment or prevention of a disease in a subject.
16. The method of any one of claims 12-13, the SMEDDS or the pharmaceutical composition of claim 14, or the use of claim 15, wherein the disease is a severe liver disease.
17. The method of any one of claims 12-13, the SMEDDS or the pharmaceutical composition of claim 14, or the use of claim 15, wherein the disease is hepatitis B (HBV), liver fibrosis, or hepatocellular carcinoma.
18. The method of any one of claims 12-13, the SMEDDS or the pharmaceutical composition of claim 14, or the use of claim 15, wherein the disease is hepatitis B (HBV).
19. The method of any one of claims 12-13, the SMEDDS or the pharmaceutical composition of claim 14, or the use of claim 15, wherein the disease is liver fibrosis.
20. The method of any one of claims 12-13, the SMEDDS or the pharmaceutical composition of claim 14, or the use of claim 15, wherein the disease is hepatocellular carcinoma.
21. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-20, wherein an area under curve (AUC) of a plot of a concentration of CRV431 in a blood of the subject over time is from about 5000 ng.hr/ml to about 150000 ng.hr/ml.
22. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-21, wherein a maximum concentration (C_{max}) of CRV431 in a blood of the subject is from about 1500 ng/ml to about 2500 ng/ml.
23. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-22, wherein a time (T_{max}) to reach a maximum concentration of CRV431 in a blood of the subject is from about 0.5 hour to about 8 hours.
24. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-23, wherein an elimination half-life ($T_{1/2}$) of CRV431 in a blood of the subject is from about 10 hours to about 200 hours.
25. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-24, wherein a concentration of CRV431 in a liver of the subject relative to a

concentration of CRV431 in a blood of the subject is from about 1 to about 20.

26. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-25, wherein the therapeutically effective amount of the SMEDDS is from about 0.5 mg/kg to about 5 mg/kg.
27. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-26, thereby a symptom of the disease in the subject is alleviated and/or a severity of the disease in the subject decreases.
28. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-27, thereby a function of a liver of the subject is improved.
29. The method, the SMEDDS, the pharmaceutical composition, or the use of any one of claims 12-28, thereby a load of a virus causing the disease decreases.
30. The SMEDDS, the pharmaceutical composition, the method, or the use of any of the preceding claims, wherein the pharmaceutical composition or the SMEDDS is stable at room temperature.
31. The SMEDDS, the pharmaceutical composition, the method, or the use of any of the preceding claims, wherein the pharmaceutical composition or the SMEDDS is stable for from at least about 25 days to at least about 200 days.
32. The SMEDDS, the pharmaceutical composition, the method, or the use of any of the preceding claims, wherein the diameter of particles formed by the pharmaceutical composition or the SMEDDS dispersed in an aqueous solution is from about 15 nm to about 40 nm.