METHODS FOR TREATING HCV

[0001] This application claims the benefit of U.S. Provisional Application No. 61/783,376, filed March 14, 2013, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to interferon-free and ribavirin-free treatment for hepatitis C virus (HCV).

BACKGROUND OF THE INVENTION

[0003] The HCV is an RNA virus belonging to the Hepacivirus genus in the Flaviviridae family. The enveloped HCV virion contains a positive stranded RNA genome encoding all known virus-specific proteins in a single, uninterrupted, open reading frame. The open reading frame comprises approximately 9500 nucleotides and encodes a single large polyprotein of about 3000 amino acids. The polyprotein comprises a core protein, envelope proteins E1 and E2, a membrane bound protein p7, and the non-structural proteins NS2, NS3, NS4A, NS4B, NS5A and NS5B.

[0004] Chronic HCV infection is associated with progressive liver pathology, including cirrhosis and hepatocellular carcinoma. Chronic hepatitis C may be treated with peginterferon-alpha in combination with ribavirin. Substantial limitations to efficacy and tolerability remain as many users suffer from side effects, and viral elimination from the body is often incomplete. Therefore, there is a need for new therapies to treat HCV infection.

BRIEF SUMMARY OF THE INVENTION

[0004a] In one aspect, there is provided the use of at least two direct acting antiviral agents (DAAs) in the manufacture of a medicament for treating HCV in a patient, wherein neither interferon nor ribavirin are administered to said patient during said treatment, and said treatment lasts for 8, 9, 10, 11 or 12 weeks, and wherein said at least two DAAs comprise:

Compound 1 or a pharmaceutically acceptable salt thereof, and

Compound 2 or a pharmaceutically acceptable salt thereof.

[0005] One aspect of the present invention features methods for treating HCV infection in a subject in need of such treatment. The methods comprise administering at least two direct acting antiviral agents (DAAs) to the subject for a duration of no more than 12 weeks, or for another duration as set forth herein. The at least two DAAs comprise Compound 1 (or a pharmaceutically acceptable salt thereof) and Compound 2 (or a pharmaceutically acceptable salt thereof). Preferably, the duration of the treatment is

12 weeks. The duration of the treatment can also be, for example, no more than 8 weeks. Preferably, the two or more DAAs are administered in amounts effective to provide a sustained virological response (SVR) or achieve another desired measure of effectiveness in the subject. The subject is not administered ribavirin during the treatment regimen. The subject is also not administered interferon during the treatment regimen. Put another way, the methods exclude the administration of interferon or ribavirin to the subject, thereby avoiding the side effects associated with interferon and ribavirin.

WHAT IS CLAIMED IS:

1. A method for treatment for HCV, comprising administering at least two direct acting antiviral agents (DAAs) to an HCV patient, wherein neither interferon nor ribavirin are administered to said patient during said treatment, and said treatment lasts for 8, 9, 10, 11 or 12 weeks, and wherein said at least two DAAs comprise:

Compound 1 or a pharmaceutically acceptable salt thereof, and

Compound 2 or a pharmaceutically acceptable salt thereof.

2. The method of claim 1, wherein said treatment lasts for 12 weeks.

3. The method of claim 1, wherein said patient is infected with HCV genotype 1.

4. The method of claim 1, wherein said patient is infected with HCV genotype 1a.

5. The method of claim 1, wherein said patient is infected with HCV genotype 2.

6. The method of claim 1, wherein said patient is infected with HCV genotype 3.

7. The method of claim 1, wherein said patient is infected with HCV genotype 4.

8. The method of claim 1, wherein said patient is infected with HCV genotype 5.

9. The method of claim 1, wherein said patient is infected with HCV genotype 6.

10. The method of claim 2, wherein said patient is infected with HCV genotype 1.

11. The method of claim 2, wherein said patient is infected with HCV genotype 1a.

12. The method of claim 2, wherein said patient is infected with HCV genotype 2.

13. The method of claim 2, wherein said patient is infected with HCV genotype 3.

14. The method of claim 2, wherein said patient is infected with HCV genotype 4.

15. The method of claim 2, wherein said patient is infected with HCV genotype 5.

16. The method of claim 2, wherein said patient is infected with HCV genotype 6.

17. The method of claim 1, wherein said patient is without cirrhosis.

18. The method of claim 1, wherein said patient is with compensated cirrhosis.

19. The method of claim 2, wherein said patient is without cirrhosis.

20. The method of claim 2, wherein said patient is with compensated cirrhosis.

21. The method of claim 1, wherein said patient is a treatment-naïve patient.

22. The method of claim 1, wherein said patient is an interferon non-responder.

23. The method of claim 2, wherein said patient is a treatment-naïve patient.

24. The method of claim 2, wherein said patient is an interferon non-responder.

WHAT IS CLAIMED IS:

1. Use of at least two direct acting antiviral agents (DAAs) in the manufacture of a medicament for treating HCV in a patient, wherein neither interferon nor ribavirin are administered to said patient during said treatment, and said treatment lasts for 8, 9, 10, 11 or 12 weeks, and wherein said at least two DAAs comprise:

Compound 1 or a pharmaceutically acceptable salt thereof, and

Compound 2 or a pharmaceutically acceptable salt thereof.

2. The use according to claim 1, wherein said treatment lasts for 12 weeks.

3. The use according to claim 1, wherein said patient is infected with HCV genotype 1.

4. The use according to claim 1, wherein said patient is infected with HCV genotype 1a.

5. The use according to claim 1, wherein said patient is infected with HCV genotype 2.

6. The use according to claim 1, wherein said patient is infected with HCV genotype 3.

7. The use according to claim 1, wherein said patient is infected with HCV genotype 4.

8. The use according to claim 1, wherein said patient is infected with HCV genotype 5.

9. The use according to claim 1, wherein said patient is infected with HCV genotype 6.

10. The use according to claim 2, wherein said patient is infected with HCV genotype 1.

11. The use according to claim 2, wherein said patient is infected with HCV genotype 1a.

12. The use according to claim 2, wherein said patient is infected with HCV genotype 2.

13. The use according to claim 2, wherein said patient is infected with HCV genotype 3.

14. The use according to claim 2, wherein said patient is infected with HCV genotype 4.

15. The use according to claim 2, wherein said patient is infected with HCV genotype 5.

16. The use according to claim 2, wherein said patient is infected with HCV genotype 6.

17. The use according to claim 1, wherein said patient is without cirrhosis.

18. The use according to claim 1, wherein said patient is with compensated cirrhosis.

19. The use according to claim 2, wherein said patient is without cirrhosis.

20. The use according to claim 2, wherein said patient is with compensated cirrhosis.

21. The use according to claim 1, wherein said patient is a treatment-naïve patient.

22. The use according to claim 1, wherein said patient is an interferon non responder.

23. The use according to claim 2, wherein said patient is a treatment-naïve patient.

24. The use according to claim 2, wherein said patient is an interferon non responder.

25. The use according to claim 1, wherein said medicament is formulated for separate administration of said DAAs.

26. The use according to claim 1, wherein said medicament is formulated for combined administration of said DAAs.

27. The use according to any one of claims 1-26, wherein said at least two DAAs is the combination of Compound 1 and Compound 2.

28. The use according to any one of claims 1-26, wherein said at least two DAAs is the combination of Compound 1 and a pharmaceutically acceptable salt of Compound 2.

29. The use according to any one of claims 1-26, wherein said at least two DAAs is the combination of Compound 2 and a pharmaceutically acceptable salt of Compound 1.

30. The use according to any one of claims 1-26, wherein said at least two DAAs is the combination of a pharmaceutically acceptable salt of Compound 1 and a pharmaceutically acceptable salt of Compound 2.