CLAIMS

1. A pharmaceutical composition for treatment of herpes simplex virus (HSV) infection, prophylaxis, or pre-exposure prophylaxis against HSV infection in a subject in need thereof comprising: a therapeutically effective amount of (a) valacyclovir or a salt or solvate thereof and (b) famciclovir or a salt or solvate thereof; and pharmaceutically acceptable excipient(s), diluent(s), carrier(s) and/or adjuvant(s).

2. A pharmaceutical composition according to Claim 1, comprising 0.5 mg/kg body weight to about 1000 mg/kg body weight of (a) or about 5 mg/kg body weight to about 50 mg/kg body weight of (a) or about 25 mg/kg body weight to about 100 mg/kg body weight of (a) or about 50 mg/kg body weight to about 250 mg/kg body weight of (a) or about 100 mg/kg body weight to about 500 mg/kg body weight of (a) and 0.5 mg/kg body weight to about 1000 mg/kg body weight of (b) or about 5 mg/kg body weight to about 50 mg/kg body weight of (b) or about 25 mg/kg body weight to about 100 mg/kg body weight of (b) or about 50 mg/kg body weight to about 250 mg/kg body weight of (b) or about 100 mg/kg body weight to about 500 mg/kg body weight of (b).

3. A pharmaceutical composition according to Claim 2, comprising (a) and (b) in a dose ratio in mg/kg of about 5:1, about 4:1, about 3:1, about 2:1, about 1:1, about 1:2, about 1:3, about 1:4, or about 1:5.

4. A pharmaceutical composition according to Claim 1, comprising about 5 mg/kg body weight to about 15 mg/kg body weight of (a) and about 2.5 mg/kg body weight to about 7.5 mg/kg body weight of (b), or about 10 mg/kg body weight to about 50 mg/kg body weight of (a) and about 5 mg/kg body weight to about 25 mg/kg body weight of (b), or about 50 mg/kg body weight to about 150 mg/kg body weight of (a) and about 20 mg/kg body weight to about 50 mg/kg body weight of (b), or about 100 mg/kg body weight to about 150 mg/kg body weight of (a) and about 50 mg/kg body weight to about 100 mg/kg body weight of (b), or about 150 mg/kg body weight to about 500 mg/kg body weight of (a) and about 100 mg/kg body weight to about 250 mg/kg body weight of (b), or about 250 mg/kg body weight to about 1000 mg/kg body weight of (a) and about 150 mg/kg body weight to about 500 mg/kg body weight of (b).

5. A pharmaceutical composition according to Claim 1, comprising from greater than 100 mg/kg to about 700 mg/kg body weight of valacyclovir and from greater than 100 mg/kg to about 500 mg/kg body weight of famciclovir.

6. A pharmaceutical composition according to Claim 1, comprising about 1 mg to about 8000 mg of valacyclovir or a salt or solvate thereof and about 1 mg to about 8000 mg famciclovir or a salt or solvate thereof, or comprising about 125 mg to about 2000 mg of valacyclovir or a salt or solvate thereof and about 60 mg to about 1000 mg famciclovir or a salt or solvate thereof.

7. A pharmaceutical composition according to Claim 1, formulated for oral administration, or comprising an oral tablet, oral capsule, or oral solution, or formulated for administration once daily or twice daily, or formulated in sustained-release form, or formulated in parenteral administration form.

8. A pharmaceutical composition according to Claim 1, additionally comprising a therapeutically effective amount of an additional antiviral agent or an HIV antiviral agent, or formulated for a female and additionally comprising a therapeutically effective amount of a contraceptive.

9. A pharmaceutical composition according to Claim 8, in which the additional antiviral agent comprises a helicase-primase inhibitor, amenamevir, N-methancocarbathymidine (N-MCT), tenofovir, emtricitabine, lamivudine, interfereon, ribavirin, boceprevir, telaprevir, simeprevir, sofosbuvir, ledipasvir, tenofovir, ombitasvir, paritaprevir, penciclovir, pritelivir, brincidofovir, cidofovir, ganciclovir, valganciclovir, valomaciclovir, or ritonavir.

10. A pharmaceutical composition according to Claim 1, in which the HSV is HSV-1, HSV-2, varicella-zoster virus (VZV), Epstein-Barr virus (human herpes virus 4), cytomegalovirus (human herpes virus 5), roseolovirus (human herpes virus 6 and 7), or Karposi's sarcoma-associated herpes virus (human herpes virus 8).

11. A pharmaceutical composition for treatment of herpes simplex virus (HSV) infection, prophylaxis, or pre-exposure prophylaxis against HSV infection in a subject in need thereof comprising: a therapeutically effective amount of greater than 100 mg/kg body weight of an antiviral agent comprising acyclovir or a salt or solvate thereof, or valacyclovir or a salt or

solvate thereof, or famciclovir or a salt or solvate thereof, or combinations thereof, whereby the risk of HSV infection in the subject is reduced.

12. A pharmaceutical composition according to Claim 11, in which the amount of the antiviral agent is from greater than 100 mg/kg to about 1000 mg/kg body weight, or in which the amount of the antiviral agent is from greater than 100 mg/kg to about 700 mg/kg body weight, or in which the amount of the antiviral agent is from greater than 100 mg/kg to about 500 mg/kg body weight, or in which the amount of the antiviral agent is from greater than 100 mg/kg to about 250 mg/kg body weight, or in which the amount of the antiviral agent is from about 125 mg/kg to about 500 mg/kg body weight.

13. A pharmaceutical composition according to Claim 11, which comprises 0.5 mg/kg to about 1000 mg/kg body weight, or 0.5 mg/kg to about 700 mg/kg body weight, or 0.5 mg/kg to about 500 mg/kg body weight, or greater than about 100 mg/kg body weight of a second antiviral agent.

14. A pharmaceutical composition according to Claim 11, which comprises valacyclovir or a salt or solvate thereof and famciclovir or a salt or solvate thereof, or comprises valacyclovir or a salt or solvate thereof and acyclovir or a salt or solvate thereof.

15. A pharmaceutical composition according to Claim 14, which comprises greater than 100 mg/kg body weight of valacyclovir and greater than 100 mg/kg body weight of famciclovir, or from greater than 100 mg/kg to about 700 mg/kg body weight of valacyclovir and from greater than 100 mg/kg to about 500 mg/kg body weight of famciclovir.

16. A pharmaceutical composition according to Claim 15, comprising about 1 mg to about 8000 mg of valacyclovir or a salt or solvate thereof and about 1 mg to about 8000 mg famciclovir or a salt or solvate thereof, or about 125 mg to about 2000 mg of valacyclovir or a salt or solvate thereof and about 60 mg to about 1000 mg famciclovir or a salt or solvate thereof.

17. A pharmaceutical composition according to Claim 14, formulated for oral administration, or comprising an oral tablet, oral capsule, or oral solution, or formulated for administration once daily or twice daily, or formulated in sustained-release form, or formulated in parenteral administration form.

18. A pharmaceutical composition according to Claim 14, additionally comprising a therapeutically effective amount of an additional antiviral agent or an HIV antiviral agent, or formulated for a female and additionally comprising a therapeutically effective amount of a contraceptive.

19. A pharmaceutical composition according to Claim 18, in which the additional antiviral agent comprises a helicase-primase inhibitor, amenamevir, N-methancocarbathymidine (N-MCT), tenofovir, emtricitabine, lamivudine, interfereon, ribavirin, boceprevir, telaprevir, simeprevir, sofosbuvir, ledipasvir, tenofovir, ombitasvir, paritaprevir, penciclovir, pritelivir, brincidofovir, cidofovir, ganciclovir, valganciclovir, valomaciclovir, or ritonavir.

20. A pharmaceutical composition according to Claim 11, in which the HSV is HSV-1, HSV-2, varicella-zoster (VZV), Epstein-Barr virus (human herpes virus 4), cytomegalovirus (human herpes virus 5), roseolovirus (human herpes virus 6 and 7), or Karposi's sarcoma-associated herpes virus (human herpes virus 8).

CLAIMS

1. Use of a combination of (a) valacyclovir or a salt or solvate thereof and (b) famciclovir or a salt or solvate thereof in the preparation of a medicament for the treatment of herpes simplex virus (HSV) infection, prophylaxis, or pre-exposure prophylaxis against HSV infection.

2. Use according to Claim 1, in which the medicament comprises 0.5 mg/kg body weight to 1000 mg/kg body weight of (a) or 5 mg/kg body weight to 50 mg/kg body weight of (a) or 25 mg/kg body weight to 100 mg/kg body weight of (a) or 50 mg/kg body weight to 250 mg/kg body weight of (a) or 100 mg/kg body weight to 500 mg/kg body weight of (a) and 0.5 mg/kg body weight to 1000 mg/kg body weight of (b) or 5 mg/kg body weight to 50 mg/kg body weight of (b) or 25 mg/kg body weight to 100 mg/kg body weight of (b) or 50 mg/kg body weight to 250 mg/kg body weight of (b) or 100 mg/kg body weight to 500 mg/kg body weight of (b).

3. Use according to Claim 2, in which the medicament comprises (a) and (b) in a dose ratio in mg/kg of 5:1, 4:1, 3:1, 2:1, 1:1, 1:2, 1:3, 1:4, or 1:5.

4. Use according to Claim 1, in which the medicament comprises 5 mg/kg body weight to 15 mg/kg body weight of (a) and 2.5 mg/kg body weight to 7.5 mg/kg body weight of (b), or 10 mg/kg body weight to 50 mg/kg body weight of (a) and 5 mg/kg body weight to 25 mg/kg body weight of (b), or 50 mg/kg body weight to 150 mg/kg body weight of (a) and 20 mg/kg body weight to 50 mg/kg body weight of (b), or 100 mg/kg body weight to 150 mg/kg body weight of (a) and 50 mg/kg body weight to 100 mg/kg body weight of (b), or 150 mg/kg body weight to 500 mg/kg body weight of (a) and 100 mg/kg body weight to 250 mg/kg body weight of (b), or 250 mg/kg body weight to 1000 mg/kg body weight of (a) and 150 mg/kg body weight to 500 mg/kg body weight of (b).

5. Use according to Claim 1, in which the medicament comprises from greater than 100 mg/kg to 700 mg/kg body weight of valacyclovir and from greater than 100 mg/kg to 500 mg/kg body weight of famciclovir.

6. Use according to Claim 1, in which the medicament comprises 1 mg to 8000 mg of valacyclovir or a salt or solvate thereof and 1 mg to 8000 mg famciclovir or a salt or solvate

thereof, or comprising 125 mg to 2000 mg of valacyclovir or a salt or solvate thereof and 60 mg to 1000 mg famciclovir or a salt or solvate thereof.

7. Use according to Claim 1, in which the medicament is formulated for oral administration, or comprises an oral tablet, oral capsule, or oral solution, or is formulated for administration once daily or twice daily, or is formulated in sustained-release form, or is formulated in parenteral administration form.

8. Use according to Claim 1, in which the medicament additionally comprises a therapeutically effective amount of an additional antiviral agent or an HIV antiviral agent, or is formulated for a female and additionally comprises a therapeutically effective amount of a contraceptive.

9. Use according to Claim 8, in which the additional antiviral agent comprises a helicase-primase inhibitor, amenamevir, N-methancocarbathymidine (N-MCT), tenofovir, emtricitabine, lamivudine, interfereon, ribavirin, boceprevir, telaprevir, simeprevir, sofosbuvir, ledipasvir, tenofovir, ombitasvir, paritaprevir, penciclovir, pritelivir, brincidofovir, cidofovir, ganciclovir, valganciclovir, valomaciclovir, or ritonavir.

10. Use according to Claim 1, in which the HSV is HSV-1, HSV-2, varicella-zoster virus (VZV), Epstein-Barr virus (human herpes virus 4), cytomegalovirus (human herpes virus 5), roseolovirus (human herpes virus 6 and 7), or Karposi’s sarcoma-associated herpes virus (human herpes virus 8).

11. Use of a therapeutically effective amount of greater than 100 mg/kg body weight of an antiviral agent comprising acyclovir or a salt or solvate thereof, or valacyclovir or a salt or solvate thereof, or famciclovir or a salt or solvate thereof, or combinations thereof in the preparation of a medicament for the treatment of herpes simplex virus (HSV) infection, prophylaxis, or pre-exposure prophylaxis against HSV infection in a subject in need thereof, whereby the risk of HSV infection in the subject is reduced.

12. Use according to Claim 11, in which the amount of the antiviral agent is from greater than 100 mg/kg to 1000 mg/kg body weight, or in which the amount of the antiviral agent is from greater than 100 mg/kg to 700 mg/kg body weight, or in which the amount of the antiviral agent is from greater than 100 mg/kg to 500 mg/kg body weight, or in which the

amount of the antiviral agent is from greater than 100 mg/kg to 250 mg/kg body weight, or in which the amount of the antiviral agent is from 125 mg/kg to 500 mg/kg body weight.

13. Use according to Claim 11, in which the medicament comprises 0.5 mg/kg to 1000 mg/kg body weight, or 0.5 mg/kg to 700 mg/kg body weight, or 0.5 mg/kg to 500 mg/kg body weight, or greater than 100 mg/kg body weight of a second antiviral agent.

14. Use according to Claim 11, in which the medicament comprises valacyclovir or a salt or solvate thereof and famciclovir or a salt or solvate thereof, or comprises valacyclovir or a salt or solvate thereof and acyclovir or a salt or solvate thereof.

15. Use according to Claim 14, in which the medicament comprises greater than 100 mg/kg body weight of valacyclovir and greater than 100 mg/kg body weight of famciclovir, or from greater than 100 mg/kg to 700 mg/kg body weight of valacyclovir and from greater than 100 mg/kg to 500 mg/kg body weight of famciclovir.

16. Use according to Claim 15, in which the medicament comprises 1 mg to 8000 mg of valacyclovir or a salt or solvate thereof and 1 mg to 8000 mg famciclovir or a salt or solvate thereof, or 125 mg to 2000 mg of valacyclovir or a salt or solvate thereof and 60 mg to 1000 mg famciclovir or a salt or solvate thereof.

17. Use according to Claim 14, in which the medicament is formulated for oral administration, or comprises an oral tablet, oral capsule, or oral solution, or is formulated for administration once daily or twice daily, or is formulated in sustained-release form, or is formulated in parenteral administration form.

18. Use according to Claim 14, in which the medicament additionally comprises a therapeutically effective amount of an additional antiviral agent or an HIV antiviral agent, or is formulated for a female and additionally comprises a therapeutically effective amount of a contraceptive.

19. Use according to Claim 18, in which the additional antiviral agent comprises a helicase-primase inhibitor, amenamevir, N-methancocarbathymidine (N-MCT), tenofovir, emtricitabine, lamivudine, interfereon, ribavirin, boceprevir, telaprevir, simeprevir,

sofosbuvir, ledipasvir, tenofovir, ombitasvir, paritaprevir, penciclovir, pritelivir, brincidofovir, cidofovir, ganciclovir, valganciclovir, valomaciclovir, or ritonavir.

20. Use according to Claim 11, in which the HSV is HSV-1, HSV-2, varicella-zoster (VZV), Epstein-Barr virus (human herpes virus 4), cytomegalovirus (human herpes virus 5), roseolovirus (human herpes virus 6 and 7), or Karposi's sarcoma-associated herpes virus (human herpes virus 8).