CLAIMS

~~1. A method of treating an autoimmune disease comprising administering orally once or twice daily a therapeutically effective amount of a pharmaceutical formulation comprising DHODH inhibitor 2-(3,5-difluoro-3'methoxybiphenyl-4-ylamino)nicotinic acid or a pharmaceutically acceptable salt thereof, wherein the autoimmune disease is selected from the group comprising relapsing-remitting multiple sclerosis, and inflammatory bowel disease; and wherein the DHODH inhibitor is administered at a dose in the range of 10 mg to 400 mg per day, with the proviso that the treatment is not used in combination with methotrexate.~~

~~2. A pharmaceutical formulation comprising DHODH inhibitor 2-(3,5-difluoro-3'methoxybiphenyl-4-ylamino)nicotinic acid or a pharmaceutically acceptable salt thereof, for use in the treatment of an autoimmune disease by oral administration once or twice daily, wherein the autoimmune disease is selected from the group comprising relapsing-remitting multiple sclerosis, and inflammatory bowel disease; and wherein the DHODH inhibitor is administered at a dose in the range of 10 mg to 400 mg per day with the proviso that the treatment is not used in combination with methotrexate.~~

~~3.~~1. Use of a pharmaceutical formulation comprising a DHODH inhibitor 2-(3,5-difluoro-3'methoxybiphenyl-4-ylamino)nicotinic acid or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of an autoimmune disease by oral administration once or twice daily, wherein the autoimmune disease is selected from the group comprising relapsing remitting multiple sclerosis and inflammatory bowel disease; and wherein the DHODH inhibitor is administered at a dose in the range of 10 mg to 400 mg per day with the proviso that the treatment is not used in combination with methotrexate.

~~4.~~2. A ~~method, inhibitor or~~ use according to ~~any one of~~ claim~~s~~ 1 ~~to 3~~, wherein the autoimmune disease is relapsing-remitting multiple sclerosis.

~~5.~~3. A ~~method, inhibitor or~~ use according to any one of claims 1 to ~~3~~2, wherein the autoimmune disease is inflammatory bowel disease.

~~6.~~4. A ~~method, inhibitor or~~ use according to claim ~~5~~3, wherein the inflammatory bowel disease is selected from Coeliac disease, Crohn's disease, and Ulcerative colitis.

~~7.~~5. A ~~method, inhibitor or~~ use according to any one of claims 1 to ~~6~~4, wherein the autoimmune disease is characterised by aberrant T cell and/or B cell activation.

~~8.~~6. A ~~method, inhibitor or~~ use according to any one of claims 1 to ~~7~~5, wherein the autoimmune disease is severe in that is not controlled by standard of care medicaments/treatments.

~~9.~~7. A ~~method, inhibitor or~~ use according to any one of claims 1 to ~~8~~6, wherein the DHODH inhibitor is employed as monotherapy.

~~10.~~8. A ~~method, inhibitor or~~ use according to any one of claims 1 to ~~8~~6, wherein the DHODH inhibitor is employed in a combination therapy.

~~11.~~9. A ~~method, inhibitor or~~ use according to claim ~~10~~8, wherein the combination therapy comprises a treatment independently selected from:

i. corticosteroids (for example oral prednisone and intravenous methylprednisolone), plasma exchange (plasmapheresis), interferon beta medications, glatiramer acetate, fingolimod, dimethyl fumarate, diroximel fumarate, teriflunomide, siponimod, cladribine, ocrelizumab, natalizumab, an anti-CD20 agent or biosimilar thereof, such as rituximab, alemtuzumab, and a Bruton's Tyrosine Kinase (BTK) inhibitor;

ii. a treatment to ease or reduce the symptoms of multiple sclerosis, for example a muscle relaxant (such as baclofen, tizanidine and cyclobenzaprine), a medication to reduce fatigue (such as amantadine, modafinil, and methylphenidate), and a medication to increase walking speed (such as dalfampridine);

iii. an antidepressant, for example duloxetine, and a tricyclic antidepressant, such as clomipramine;

iv. interferon beta (IFN-β), such as interferon beta-1a or interferon beta-1b;

v. an anti-CD20 agent or a biosimilar thereof, for example Rituxan (rituximab), a Rituximab biosimilar, Gazyva, Kesimpta, Ocrevus (ocrelizumab), Ruxience, Truxima, Zevalin, Arzerra, AcellBia, HLX01, Reditux, Ritucad and Zytux; and

vi. a Bruton's Tyrosine Kinase (BTK) inhibitor, for example Ibrutinib, Acalabrutinib, Zanubrutinib, Evobrutinib, ABBV-105, Fenebrutinib, GS-4059, Spebrutinib and HM71224.

~~12.~~10. A ~~method, inhibitor or~~ use according to any one of claims ~~10~~ 8 to ~~11~~9, wherein the combination therapy comprises a purine synthesis inhibitor, such as azathioprine.

~~13.~~11. A ~~method, inhibitor or~~ use according to any one of claims 1 to ~~12~~10, wherein the DHODH inhibitor is administered once daily.

12. A use according to any one of claims 1 to 10, wherein the DHODH inhibitor is administered twice daily.

~~14.~~13. A ~~method, inhibitor or~~ use according to any one of claims 1 to 13, wherein the DHODH inhibitor is administered at a dose in the range of 100 to 400 mg per day.

14. A use according to any one of claims 1 to 13, wherein the DHODH inhibitor is administered at a dose of 400 mg per day.

15. A use according to any one of claims 1 to 13, wherein the DHODH inhibitor is administered at a dose of 300 mg per day.

16. A use according to any one of claims 1 to 13, wherein the DHODH inhibitor is administered at a dose of 200 mg per day.

17. A use according to any one of claims 1 to 13, wherein the DHODH inhibitor is administered at a dose of 200 mg twice per day.

18. A use according to any one of claims 1 to 13, wherein the DHODH inhibitor is administered at a dose of 150 mg twice per day.

19. A use according to any one of claims 1 to 13, wherein the DHODH inhibitor is administered at a dose of 100 mg twice daily.

20. A use according to any one of claims 1 to 13, wherein the DHODH inhibitor is administered at a dose of 50 mg twice per day.