

CLAIMS:

1. Use of LOU064 or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of multiple sclerosis.
2. The use according to claim 1, wherein LOU064 is to be administered orally at a dose of about 50 mg to about 150 mg twice daily.
3. The use according to claim 1 or 2, wherein LOU064 is to be administered orally at a dose of about 100 mg twice daily.
4. The use according to any one of the preceding claims, wherein the treatment is a long-term treatment.
5. The use according to any one of the preceding claims, wherein the multiple sclerosis is selected from relapsing multiple sclerosis, in particular clinically isolated syndrome (CIS), relapsing-remitting multiple sclerosis (RRMS) and secondary progressive multiple sclerosis (SPMS), in particular active SPMS.
6. The use according to any one of the preceding claims, wherein the patients are switched from a drug of an earlier disease-modifying therapy to LOU064.
7. The use according to claim 6, wherein the drug of the earlier disease-modifying therapy is selected from a B cell and/or T cell inhibitor, teriflunomide, mitoxantrone, dimethyl fumarate, cladribine, fingolimod, siponimod, ponesimod, glatiramer acetate, and interferon (e.g beta interferon).
8. The use according to claim 6 or 7, wherein the earlier disease-modifying therapy lacks efficacy.
9. The use according to any one of claims 6 to 8, wherein the patient lacks tolerability for the earlier disease-modifying therapy.
10. The use according to any one of claims 6 to 9, wherein the earlier disease-modifying therapy is discontinued before initiation of LOU064 administration.
11. The use according to any one of the preceding claims, wherein LOU064 is selected if the patient is planning to get pregnant within the next 12 months.
12. The use according to any one of the preceding claims, wherein LOU064 is selected if the patient will undergo chemotherapy within the next 12 months.
13. The use according to any one of the preceding claims, wherein the treatment is a monotherapy.
14. The use according to any one of the preceding claims, wherein LOU064 is not to be administered concomitantly with a strong inhibitor of CYP3A.
15. The use according to any one of the preceding claims, wherein LOU064 is not to be administered concomitantly with a strong inducer of CYP3A4.

16. The use according to any one of the preceding claims, wherein a patient acutely or previously infected by COVID-19 is to be treated.
17. The use according to any one of the preceding claims, wherein the treatment is continued during COVID-19 infection.
18. The use according to any one of claims 1-16, wherein the treatment is interrupted during COVID-19 infection and continued after overcoming the infection.
19. The use according to any one of the preceding claims, wherein the treatment is an ethnic insensitive treatment.
20. The use according to any one of the preceding claims, wherein LOU064 is to be administered after a relapse.
21. The use according to any one of the preceding claims, wherein LOU064 is to be administered after the detection of at least one Gd⁺ lesion.
22. The use according to any one of the preceding claims, wherein LOU064 is to be administered after the detection of new or enlarging T2 lesions.
23. The use according to any one of the preceding claims, wherein the patient is an adult.
24. The use according to any one of the preceding claims, wherein the patient achieves at least one of the following:
 - a reduced mean total number of gadolinium-enhancing lesions as compared to untreated patients and/or as compared to patients receiving another disease-modifying treatment selected from interferon, teriflunomide, glatiramer acetate and dimethyl fumarate, preferably interferon, teriflunomide and dimethyl fumarate, more preferably teriflunomide or interferon,
 - a reduced annualized relapse rate as compared to untreated patients and/or as compared to patients receiving another disease-modifying treatment selected from interferon, teriflunomide, glatiramer acetate and dimethyl fumarate, preferably interferon, teriflunomide and dimethyl fumarate, more preferably teriflunomide or interferon,
 - a longer time to reach 3-month confirmed disability progression as compared to patients receiving another disease-modifying treatment selected from interferon, teriflunomide, glatiramer acetate and dimethyl fumarate, preferably interferon, teriflunomide and dimethyl fumarate, more preferably teriflunomide or interferon,within up to 24 months, preferably 12-24 months of treatment.
25. The use according to any one of the preceding claims, wherein by week 12 or by week 24 of treatment the levels of alanine aminotransferase (ALT), aspartate

aminotransferase (AST), and lipase do not change by more than 10% as compared to the baseline level at the start of therapy.

26. The according to any one of the preceding claims, wherein the treatment is at least as effective in reducing the annual relapse rate as a CD20-depleting therapy.
27. The use according to any one of the preceding claims, wherein the patient is vaccinated during LOU064 therapy, in particular vaccinated with non-live vaccines.
28. The use according to any one of the preceding claims, wherein LOU064 is to be administered in the form of a suitable oral pharmaceutical formulation comprising nanosized particles of LOU064.
29. The use according to any one of the preceding claims, wherein LOU064 is to be administered in the form of a suitable oral pharmaceutical formulation comprising nanosized particles of LOU064 having a mean particle size as measured by PCS of between about 50 nm to about 750 nm.
30. The use according to any one of the preceding claims, wherein LOU064 is to be administered in the form of a suitable oral pharmaceutical formulation comprising LOU064 and binder at a weight ratio of about 2 : 1.
31. The use according to any one of the preceding claims, wherein LOU064 is to be administered in the form of a suitable oral pharmaceutical formulation comprising LOU064, binder and surfactant at a weight ratio of about 2 : 1 : 0.08.
32. The use according to any one of claims 1 to 29, wherein LOU064 is to be administered in the form of a suitable oral pharmaceutical formulation comprising LOU064 and binder at a weight ratio of about 1 : 1.
33. The use according to any one claims 1 to 29 and 32, wherein LOU064 is to be administered in the form of a suitable oral pharmaceutical formulation comprising LOU064, binder and surfactant at a weight ratio of about 1 : 1 : 0.05.
34. The use according to any one of the preceding claims, wherein LOU064 is to be administered in the form of a suitable oral pharmaceutical formulation comprising LOU064, polyvinylpyrrolidone-vinyl acetate copolymer as a binder and sodium lauryl sulfate as a surfactant.
35. The according to any one of the preceding claims, wherein LOU064 is to be co-administered with oral contraceptives.
36. LOU064 or a pharmaceutically acceptable salt thereof for use as a medicament, wherein preferably the medicament is to be administered orally at a dose of about 50 mg to about 150 mg twice daily.