Patent claims

1. Use of cladribine for the manufacture of a medicament for the oral treatment of an autoimmune disorder in a patient in need thereof, wherein said medicament is to be administered to said patient according to the following steps comprising:
(a) optionally administering said medicament during one or more treatment periods orally to a patient at fixed dose of cladribine per patient, per body weight and per treatment period, wherein said fixed dose of cladribine is selected from the range of 1.0 mg/kg to 3.0 mg/kg,
(b) identifying a patient at risk of acquiring an infection,
(c) vaccinating the patient at risk of acquiring an infection with a vaccine against said infection, and
d) optionally administering said medicament during one or more treatment periods orally to a patient at fixed dose of cladribine per patient, per body weight and per treatment period, wherein said fixed dose of cladribine is selected from the range of 1.0 mg/kg to 3.0 mg/kg,
with the proviso that said treatment comprises one or more treatment periods in which cladribine is to be administered, and
with the further proviso that said fixed dose of cladribine per patient is about the same in all of the one or more treatment periods wherein cladribine is to be administered,
thereby treating said patient against said autoimmune disorder and limiting the risk of said patient of acquiring said infection.

2. The use according to claim 1,
i) wherein the treatment comprises two or more treatment periods in which cladribine is to be administered, each with a duration from about 1 to about 3 months,
ii) wherein each of said two or more treatment periods are separated by a period in which no cladribine is to be administered to said patient, and
iii) wherein each of the periods in which no cladribine is to be administered to said patient has a duration of at least 9 months.

3. The use according to one or more of the preceding claims, said treatment comprising:
(a) administering cladribine during 1 or 2 treatment periods orally to a patient at

fixed dose per patient, per body weight and per treatment period, wherein said fixed dose is selected from the range of 1.0 mg/kg to 3.0 mg/kg,
(b) identifying a patient at risk of acquiring an infection,
(c) vaccinating the patient at risk of acquiring an infection with a vaccine against said infection, and
d) administering cladribine during 0 or 1 treatment periods orally to a patient at fixed dose per patient, per body weight and per treatment period, wherein said fixed dose is selected from the range of 1.0 mg/kg to 3.0 mg/kg.

4. The use according to one or more of the preceding claims, said treatment comprising:
(a) administering cladribine during 0 or 1 treatment periods orally to a patient at fixed dose per patient, per body weight and per treatment period, wherein said fixed dose is selected from the range of 1.0 mg/kg to 3.0 mg/kg,
(b) identifying a patient at risk of acquiring an infection,
(c) vaccinating the patient at risk of acquiring an infection with a vaccine against said infection, and
d) administering cladribine during 1 or 2 treatment periods orally to a patient at fixed dose per patient, per body weight and per treatment period, wherein said fixed dose is selected from the range of 1.0 mg/kg to 3.0 mg/kg.

5. The use according to one or more of the preceding claims, wherein
i) identifying a patient at risk of acquiring an infection according to step (b), and/or
ii) vaccinating said patient according to step (c) take place
a) within a timeframe of about 4 weeks prior to a treatment period wherein cladribine is orally administered to said patient, and/or
b) within a timeframe of about 4 weeks after a treatment period wherein cladribine is orally administered so said patient.

6. The use according to one or more of the preceding claims, wherein said treatment comprises at least 2 treatment periods wherein cladribine is to be orally administered to said patient, and wherein vaccinating said patient according to step (c) takes place within about 4 weeks prior to the first treatment period wherein Cladribine is to be orally administered to said patient, or within about 4 weeks after the last treatment

period wherein cladribine is to be orally administered to said patient.

7. The use according to one or more of the preceding claims, wherein said said treatment comprises two treatment periods wherein cladribine is to be orally administered to said patient, and wherein vaccinating said patient according to step (c) takes place within a timeframe starting about 2 weeks before the beginning of the first treatment period in which cladribine is to be orally administered to said patient, and ending within about 2 weeks after the end of the second treatment period wherein Cladribine is to be orally administered to said patient.

8. The use according to claim 6 or 7,
wherein vaccinating said patient according to step (c) takes place at any time as specified in claim 6 or 7, except for the about 4 weeks before and/or about 4 weeks after the lowest B-cell count determined in the blood of the respective subject during a timeframe set by the beginning of two adjacent treatment periods wherein cladribine is to be orally administered to said patient.

9. The use according to claim 6, 7 or 8,
wherein vaccinating said patient according to step (c) takes place at any time as specified in claim 6, 7 or 8, except for the time period of 5 to 10 weeks, 6 to 11 weeks, 5 to 13 weeks or 6 to 14 weeks after the beginning of the respective treatment period wherein cladribine is to be orally administered to said patient.

10. The use according to one or more of the preceding claims, wherein said vaccination in step(c) comprises administering to said patient a vaccine in 2 to 6 separate doses, wherein said 2 to 6 separate doses are administered to the patient on different days within a timeframe of about 1 to 12 weeks, preferably 1 to 6 weeks and especially 2-4 weeks.

11. Use of Cladribine for the manufacture of a medicament for the treatment of an autoimmune disorder and reducing the risk of an infection in a subject in need thereof, said treatment comprising
a) orally administering cladribine to said subject within the treatment period of about 2 months, in which treatment period a fixed dose of cladribine per patient, selected

from 1.0 mg/kg to 3.0 mg/kg, is orally administered to said patient, wherein said treatment period is followed by a cladribine free period of at least 9 months in which no cladribine is to be administered to said patient, and

b) vaccinating or immunising said subject against said infection within a timeframe

i) beginning less than 4 weeks, preferably less than 3 weeks and especially less than 2 weeks, before said treatment period of about 2 months wherein cladribine is to be orally administered to said patient, and ending with the beginning of the second treatment month in the respective treatment period wherein cladribine is to be orally administered to said patient, and/or

ii) beginning with the end of the second treatment month in the said treatment period wherein cladribine is to be orally administered to the patient, and ending with the end of the cladribine free period of at least 9 month that is directly following that treatment period.

12. A use Cladribine for the manufacture of a medicament for the treatment of an autoimmune disorder and reducing the risk of an infection in a subject in need thereof, said treatment comprising,

a) at least 2 treatment periods of about 2 months duration each, wherein cladribine is to be orally administered to said subject at a fixed dose per patient and per treatment period, wherein said fixed dose of cladribine is selected from the range of 1.0 mg/kg to 3.0 mg/kg, preferably 1.5 mg/kg to 2.0 mg/kg, and wherein each treatment period is to be followed by a cladribine free period of at least 9 months, in which no cladribine is to be administered to said subject, and

b) at least one vaccination period of up to 4 weeks, preferably up to 2 weeks, wherein said subject is vaccinated or immunised one or more times against said infection, wherein said vaccination period starts

i) less than 4 weeks, preferably less than 3 weeks and especially less than 2 weeks, before the beginning of a said treatment period,

ii) within the first or second week of a said treatment period, and/or

iii) with a timeframe set by the end of a said treatment period wherein cladribine is to be orally administered to said subject, and ending with the end of a subsequent cladribine free period of at least 9 months, in which no cladribine is to be administered to said subject, which cladribine free period preferably directly follows

a said treatment period.

13. Use of cladribine for the manufacture of a medicament for the treatment of an autoimmune disorder and reducing the risk of an infection in a subject in need thereof, said treatment comprising,
a) 2 treatment periods of about 2 months duration each, wherein cladribine is to be orally administered to said subject at a fixed dose per patient and per treatment period, wherein said fixed dose of cladribine is selected from the range of 1.5 mg/kg to 2.0 mg/kg, and wherein each treatment period is to be followed by a cladribine free period of at least 9 months, preferably at least 10 months, in which no cladribine is to be administered to said subject, and
b) one or two vaccination periods of up to 4 weeks, preferably up to 2 weeks, wherein said subject is vaccinated or immunised one or more times against said infection,
wherein each of said vaccination periods starts, preferably independently selected from each other,
i) less than 4 weeks, preferably less than 3 weeks and especially less than 2 weeks, before the beginning of a said treatment period,
ii) within the first or second week of a said treatment period, and/or
iii) at any time within a timeframe set by the end of a said treatment period wherein cladribine is to be orally administered to said subject, and by end of the subsequent cladribine free period of at least 9 or preferably 10 months, in which no cladribine is to be administered to said subject, preferably a said cladribine free period which directly follows a said treatment period.

14. Use of cladribine for the manufacture of a medicament for the treatment an autoimmune disorder and reducing the risk of an infection in a subject in need thereof, said treatment comprising,
a) 2 treatment periods of about 2 months duration each, wherein cladribine is to be orally administered to said subject at a fixed dose per patient and per treatment period, wherein said fixed dose of cladribine is selected from the range of 1.5 mg/kg to 2.0 mg/kg, and wherein each treatment period is to be followed by a cladribine free period of at least 9 months, preferably at least 10 months, in which no cladribine is to be administered to said subject, and

b) one or two vaccination periods of up to 4 weeks, preferably up to 2 weeks, wherein said subject is vaccinated or immunised one or more times against said infection,

wherein each said vaccination periods, independently from each other,

i) starts less than 4 weeks, preferably less than 3 weeks and especially less than 2 weeks, before the beginning of a said treatment period, and ends 6 weeks, preferably 4 weeks and especially 2 weeks, after the beginning of said treatment period, or

ii) starts with the end of said treatment period, starts 1 week after the end of said treatment period, or starts two weeks after the end of said treatment period.

15. The use according to one or more of the preceding claims, wherein said subject

i) is vaccinated one or more times, preferably once or twice, within a timeframe starting two weeks before the beginning of said treatment period, and ending four weeks after the beginning of said treatment period,

and/or

ii) is vaccinated one or more times, preferably once or twice, within a timeframe starting with the end of said treatment period, and ending two weeks, three weeks or four weeks after the end of said treatment period.

16. The use according to one or more of the preceding claims, wherein said subject to be vaccinated or immunised is having lymphopenia Grade ≥1, lymphopenia Grade ≥2, or lymphopenia (Grade ≥3), at the beginning or during said vaccination period.

17. The use according to one or more of the preceding claims, wherein said subject is vaccinated with one or more vaccines, selected from the group consisting of inactivated vaccines, subunit vaccines, recombinant vaccines, polysaccharide vaccines, conjugate vaccines and toxoid vaccines, and/or combinations thereof.

18. The use according to one or more of the preceding claims, wherein the autoimmune disorder is selected from the group consisting of Multiple Sclerosis (MS), Rheumatoid Arthritis (RA), Systemic Lupus Erythematosus (SLE), Neuromyelitis Optica Spectrum Disorders (NMOSD) and Myasthenia Gravis (MG), preferably Multiple Sclerosis (MS), Neuromyelitis Optica Spectrum Disorders (NMOSD) and

Myasthenia Gravis (MG).

19. The use according to one or more of the preceding claims, wherein the autoimmune disorder is Multiple Sclerosis (MS).

20. The use according to one or more of the preceding claims, wherein the autoimmune disorder is Multiple Sclerosis (MS), including one or more indications selected from the group consisting of relapsing forms of Multiple Sclerosis (RMS), relapsing-remitting multiple sclerosis (RRMS), secondary progressive Multiple Sclerosis (SPMS) and primary progressive multiple Sclerosis (PPMS).

21. The use according to one or more of the preceding claims, the treatment comprising: administering cladribine during one or more treatment periods orally to a patient at fixed dose per patient, per body weight and per treatment period, wherein said fixed dose is selected from the range of about 1.0 mg/kg to about 3.0 mg/kg, and wherein the cladribine is to be administered to said patient in a manner that the effective or bioavailable amount of cladribine in said patient is a fixed dose per patient, per body weight and per treatment period selected from the range of about 0.5 mg/kg to about 1.6 mg/kg, preferably 0.8 +/- 0.2 mg/kg.

22. The use according claim 34, wherein said effective or bioavailable amount of cladribine in said patient at a fixed dose per patient, per body weight and per treatment period in the range of about 0.3 mg/kg to about 2.0 mg/kg is achieved by administering an oral dosage form providing a bioavailability of cladribine in said patient selected from the range consisting of about 30% to about 100%, preferably about 40% to 50%.

23. The use according to one or more of the preceding claims, wherein the autoimmune disorder to be treated is Multiple Sclerosis (MS), and that subject to be treated is having high disease activity (HDA).

24. The use according to one or more of the preceding claims, wherein the subject to be treated is aged over 30 years, over 40 years, over 50 years, over 60 years, or over 70

years.

25. The use according to one or more of the preceding claims, wherein the patients are having Grade 0 to Grade 3 lymphocytopenia, more preferably Grade 1 to Grade 3 lymphocytopenia and especially Grade 1 to Grade 2 lymphocytopenia or Grade 2 to Grade 3 lymphocytopenia, at the time the vaccination is performed or is to be performed.

26. Use of cladribine for the manufacture of a medicament for the treatment of an autoimmune disorder in a patient in need thereof, the said treatment comprising:
(i1) administering orally to said patient a cumulative dosage of 3.5 mg, preferably +/- 0.5 mg, of cladribine per kilogram of body weight (mg/kg) of said patient, wherein
(i2) said cumulative dosage is divided into 2 yearly treatment courses of 1.75 mg, preferably +/- 0.25 mg, of cladribine per kilogram of bodyweight of said patient and per treatment course, wherein
(i3) each treatment course is divided into 2 treatment cycles, wherein
(i4) each treatment cycle dosage is about 10 mg or about 20 mg per day, orally administered daily for 4 or 5 consecutive days depending on said bodyweight, and preferably said treatment cycle dosage is to be administered within the first week of the respective treatment cycle, wherein
(ii1) the first treatment course/first treatment cycle can be started any time, and
(ii2) the first treatment course/second treatment cycle, or first treatment course/second treatment cycle dose, is then administered about 23 to 27 days after the last dose of said first treatment course/first treatment cycle, preferably as described in section (i4),
(iii1) administering orally to said patient the second treatment course/first treatment cycle, or second treatment course/first treatment cycle dose, at least 43 weeks after the last dose of the first treatment course/second treatment cycle, preferably as described in section (i4), and
(iii2) the second treatment course/second treatment cycle about 23 to 27 days after the last dose of the second treatment course/first treatment cycle, preferably as described in section (i4), and
iv) vaccinating said patient, preferably
(iv1) at least once between the start of the first treatment course/first treatment cycle

and the end of the first treatment course, or during the two weeks before the start of said first treatment course/first treatment cycle,
and/or
iv2) at least once between the start of the second treatment course/first treatment cycle and the end of the second treatment course, or during the two weeks before the start of said second treatment course/first treatment cycle,
with one or more vaccines, selected from group consisting of anti-viral vaccines and anti-bacterial vaccines.

27. The use according to one or more of the preceding claims, and especially according to claim 45, wherein vaccinating said patient takes place
(iv1) at least once between the start of the first treatment course/first treatment cycle and the end of the first treatment course, or during the week before the start of said first treatment course/first treatment cycle,
and/or
iv2) at least once between the start of the second treatment course/first treatment cycle and the end of the second treatment course, or during the week before the start of said second treatment course/first treatment cycle.

28. The use according to one or more of the preceding claims, wherein vaccinating said patient takes place
(iv1) at least once between the start of the first treatment course/first treatment cycle and the end month 10 or month 11 of said first treatment course, and/or during one of the two weeks, preferably during the last week, before the start of said first treatment course/first treatment cycle;
and/or
iv2) at least once between the start of the second treatment course/first treatment cycle and the end of said second treatment course, preferably at least once between the start of said second treatment course/first treatment cycle and the end of month 7, month 8, month 9 or month 10 of said second treatment course, and/or during one of the two weeks, preferably during the last week, before the start of said second treatment course/first treatment cycle.

29. The use according to one or more of the preceding claims, wherein said at least two separate vaccinations, preferably said two vaccinations and/or said 2 separate doses or shots are separated
by about 1 to 6 weeks, preferably about 2 to 5 weeks and especially about 3 weeks or about 4 weeks.

30. The use according to one or more of the preceding claims, wherein vaccinating said patient at least once comprises vaccinating said patient at least twice with a vaccine and/or using two or more separate doses or shots of vaccine, wherein the target virus/viruses or target bacterium/bacteria of said vaccine is the same for each said vaccinating and/or each said dose or shot.

31. The use according to one or more of the preceding claims, wherein vaccinating said patient at least once comprises vaccinating said patient at least twice and/or using two or more separate doses or shots of vaccine, wherein the vaccine is very similar, the same or essentially identical for each vaccination and/or in each dose or shot of the vaccine.

32. The use according to one or more of the preceding claims, wherein two vaccinations are administered to a said patient, and
a) one vaccination of said two vaccinations is to be administered to a said patient
a1) within treatment year 1/the first treatment course in which cladribine is to be orally administered, or
a2) within treatment year 2/the second treatment course in which cladribine is to be orally administered,
preferably according to the timeframes given in one or more of the preceding claims, and
b) one vaccination is given
b1) outside treatment year 1/the first treatment course in which cladribine is to be orally administered, or
b2) outside treatment year 2/the second treatment course in which cladribine is to be orally administered,
preferably within 1 to 3 weeks, more preferably 1 to 2 weeks and especially one week, before the beginning of the respective treatment year/the respective treatment

course.

33. The use according to one or more of the preceding claims, wherein two doses or two shots of the same vaccine are administered to a said patient, and
a) one dose or shot of said vaccine is to be administered to a said patient
a1) within treatment year 1/the first treatment course in which cladribine is to be orally administered, or
a2) within treatment year 2/the second treatment course in which cladribine is to be orally administered,
preferably according to the timeframes given in one or more of the preceding claims, and
b) one dose or shot of said vaccine is given
b1) outside treatment year 1/the first treatment course in which cladribine is to be orally administered, or
b2) outside treatment year 2/the second treatment course in which cladribine is to be orally administered,
preferably within 1 to 3 weeks, more preferably 1 to 2 weeks and especially one week, before the beginning of the respective treatment year/the respective treatment course.

34. The use according to one or more of the preceding claims, wherein two vaccinations are administered to a said patient, and wherein both vaccinations are administered to a said patient either
a) within treatment year 1/the first treatment course in which cladribine is to be orally administered, or
b) within treatment year 2/the second treatment course in which cladribine is to be orally administered,
preferably according to the timeframes given in one or more of the preceding claims.

35. The use according to one or more of the preceding claims, wherein vaccinating said patient comprises vaccinating said patient twice using two separate doses or shots of vaccine, wherein the vaccine is very similar, the same or essentially identical for each vaccination and in each dose or shot of the vaccine.

36. The use according to one or more of the preceding claims, and especially according to one or more of claims 58 to 74, wherein said vaccine is
a) selected from the group consisting of: (anti-)varicella zoster virus vaccines, (anti-)herpes zoster virus vaccines, attenuated live (anti-)varicella zoster virus vaccines, attenuated live (anti-)herpes zoster virus vaccines, inactive (anti-)varicella zoster virus vaccines, inactivated and/or recombinant (anti-)varicella zoster virus vaccines, and inactivated and/or recombinant (anti-)herpes zoster virus vaccines;
and/or
b) selected from the group consisting of: mRNA-based (anti-)SARS-CoV-2/COVID-19 virus vaccines, Vector-based (anti-)SARS-CoV-2/COVID-19 virus vaccines, Adenovirus/Vector-based (anti-)SARS-CoV-2/COVID-19 virus vaccines, Virus-Like Particles (VLPs) based (anti-)SARS-CoV-2/COVID-19 virus vaccines, DNA-based (anti-)SARS-CoV-2/COVID-19 virus vaccines,
Protein-based (anti-)SARS-CoV-2/COVID-19 virus vaccines, Inactivated Virus-based (anti-)SARS-CoV-2/COVID-19 virus vaccines, and Dead Virus-based (anti-)SARS-CoV-2/COVID-19 virus vaccines.

37. The use according to one or more of the preceding claims, and especially according to one or more of claims 58 to 75 or 59 to 75, wherein said vaccine is a recombinant, adjuvanted herpes zoster vaccine, preferably a recombinant, adjuvanted herpes zoster vaccine that comprises recombinant varicella zoster virus glycoprotein E, and especially is SHINGRIX®.

38. The use according to one or more of the preceding claims, wherein said vaccine is a recombinant, adjuvanted herpes zoster vaccine, preferably a recombinant, adjuvanted herpes zoster vaccine that comprises recombinant varicella zoster virus glycoprotein E, and especially is SHINGRIX®, and wherein said first vaccination, said first dose and/or said first shot is separated from said second vaccination, said second dose and/or said second shot
i) by a time period of 2 to 6 weeks, preferably 3 to 5 weeks and especially about 4 weeks or about a month,
ii) by a time period of 6 to 11 weeks, preferably 7 to 10 weeks and especially about 8 to 9 weeks or about two months, or

iii) by a time period of 2 to 8 months, preferably 2 to 7 months and especially about 3 to 6 months.

39. Use of cladribine for the manufacture of a medicament for the treatment of multiple sclerosis (MS) in a patient in need thereof, said treatment comprising
a) treating said patient with cladribine tablets (MAVENCLAD®), preferably as described in one or more of the preceding claims, and
b) vaccinating said patient with a non-live varicella zoster vaccine (SHINGRIX®), wherein said patient is vaccinated with said vaccine once (first dose) in weeks 2 to 4 and then (second dose) in weeks 10 to 12, which weeks are counted from the day on which said patient received the first dose of said cladribine tablets, with the possibility to delay the Administration of said second dose of said vaccine up to 6 months after the administration of said first dose of said vaccine.

40. Use of cladribine for the manufacture of a medicament for the treatment of multiple sclerosis (MS) in a patient in need thereof, said treatment comprising
a) treating said patient with cladribine tablets (MAVENCLAD®), preferably as described in one or more of the preceding claims, and
b) vaccinating said patient with a non-live varicella zoster vaccine (SHINGRIX®), wherein said patient is vaccinated with said vaccine once (first dose) in weeks 2 to 4 and then (second dose) in weeks 10 to 12, which weeks are counted from the day on which said patient received the first dose of said cladribine tablets, with the possibility to delay the Administration of said second dose of said vaccine up to 6 months after the administration of said first dose of said vaccine.

41. Use of cladribine for the manufacture of a medicament for the treatment of multiple sclerosis (MS) in a patient in need thereof, said treatment comprising
a) treating said patient with cladribine tablets (MAVENCLAD®), preferably as described in one or more of the preceding claims, and
b) vaccinating said patient with a non-live varicella zoster vaccine (SHINGRIX®), wherein said patient is vaccinated with said vaccine once (first dose) in month 1 and then (second dose) in months 3 to 8 and preferably months 3 to 6, counted from the day on which said patient received the first dose of said cladribine tablets, and wherein said first dose of said vaccine and said second dose of said vaccine are

preferably administered 1 to 7 months apart from each other, more preferably 2 to 6 months apart from each other and especially 2 to 3 months or 3 to 6 months apart from each other.

42. Use of cladribine for the manufacture of a medicament for the treatment of multiple sclerosis (MS) in a patient in need thereof, said treatment comprising
a) treating said patient with cladribine tablets (MAVENCLAD®), preferably as described in one or more of the preceding claims, and
b) vaccinating said patient with a non-live varicella zoster vaccine (SHINGRIX®), wherein said patient is vaccinated with said vaccine twice, preferably by administering a first dose and a second dose 2 to 6 months apart from each other and preferably about two months or about three months apart from each other, wherein said first dose of said vaccine administered in months 4 to 10 and especially in months 5 to 8, counted from the day on which said patient received the first dose of said cladribine tablets.

43. The use according to any one of claims 39 to 42, wherein said patient is antibody-negative to varicella zoster virus, preferably antibody-negative to varicella zoster virus prior to said vaccination with said non-live varicella zoster vaccine and/or prior to receiving the first dose of said cladribine tablets.

44. Use of cladribine for the manufacture of a medicament for the treatment of multiple sclerosis (MS) in a patient in need thereof, said treatment comprising
a) treating said patient with cladribine tablets (MAVENCLAD®), preferably as described in one or more of the preceding claims, and
b) vaccinating said patient at least once with a vaccine, wherein said at least one vaccination takes place during months 3 to 8 and especially during months 3 to 6, counted from the day on which said patient received the first dose of said cladribine tablets.

45. Use of cladribine for the manufacture of a medicament for the treatment of multiple sclerosis (MS) in a patient in need thereof, said treatment comprising
a) treating said patient with cladribine tablets (MAVENCLAD®), preferably as described in one or more of the preceding claims, and

b) vaccinating said patient at least once with a vaccine, preferably at least twice with a vaccine and especially twice with a vaccine,

b1) wherein a first vaccination takes place either 1 or 2 weeks prior or 1 or 2 weeks after to the day on which said patient receives the first dose of said cladribine tablets, and optionally

wherein at least one subsequent vaccination takes place 2 to 4 weeks or 3 to 10 weeks after that first vaccination took place.

46. Use of cladribine for the manufacture of a medicament for the treatment of multiple sclerosis (MS) in a patient in need thereof, said treatment comprising

a) treating said patient with cladribine tablets (MAVENCLAD®), preferably as described in one or more of the preceding claims, and

b) vaccinating said patient at least once with a vaccine, preferably at least twice with a vaccine and especially twice with a vaccine,

b1) wherein a first vaccination takes place either 1 or 2 weeks prior or 1 or 2 weeks after to the day on which said patient receives the first dose of said cladribine tablets, and optionally

wherein at least one subsequent vaccination takes place 2 to 8 months or 2 to 6 months after that first vaccination took place.

47. Use of cladribine for the manufacture of a medicament for the treatment of multiple sclerosis (MS) in a patient in need thereof, said treatment comprising

a) treating said patient with cladribine tablets (MAVENCLAD®), preferably as described in one or more of the preceding claims, and

b) vaccinating said patient at least once with a vaccine, preferably at least twice with a vaccine and especially twice with a vaccine,

b1) wherein a first vaccination takes place either 1 or 2 weeks prior or 1 or 2 weeks after to the day on which said patient receives the first dose of said cladribine tablets, and optionally

wherein at least one subsequent vaccination takes place within month 2 to 12, preferably month 2 to 10 and especially month 3 to 9, counted from the day on which said patient received the first dose of said cladribine tablets.

48. The use according to one or more of the preceding claims, wherein said day on which said patient receives the first dose of said cladribine tablets is
a) the first day of the first treatment year (treatment year 1, or the first treatment course) with respect to cladribine treatment, preferably cladribine treatment as described in one or more of the preceding claims,
and/or
b) the first day of the second treatment year (treatment year 2, or the second treatment course) with respect to cladribine treatment, preferably cladribine treatment as described in one or more of the preceding claims.

49. The use according to one or more of the preceding claims, wherein in the above described uses, all the recommendations and timelines for vaccinating patients and/or using said vaccines given with regard to the first treatment course, the first treatment year and/or treatment year 1, preferably hold true also for the second treatment course, the second treatment year and/or treatment year 2, respectively, and, if applicable, for any subsequent treatment course, or treatment year.

50. The use according to one or more of the preceding claims, wherein each of said 2 yearly treatment courses, preferably said first treatment course and/or said second treatment course, has a duration, preferably independently selected for each treatment course, of about 1 year, preferably of about 12 months, more preferably of 46 to 54 weeks, more preferably of 48-53 weeks and especially of about 48 or about 52 weeks.