Claims:

1. Cladribine for use in the oral treatment of patients suffering from progressive forms of Multiple Sclerosis, wherein said Cladribine is to be orally administered to each patient at fixed dose per patient, per body weight and per treatment year, wherein said fixed dose is selected from the range of 1.5 mg/kg to 4.0 mg/kg.

2. Cladribine for use according to claim 1, wherein said fixed dose is selected from the range of 1.5 mg/kg to 2.0 mg/kg.

3. Cladribine for use according to claim 1 and/or 2, wherein said fixed dose per patient is 1.75 mg/kg per treatment year with a maximum deviation of +/- 0.2 mg/kg.

4. Cladribine for use according to claim 1, 2 and/or 3, where said progressive forms of multiple sclerosis comprise Primary Progressive Multiple Sclerosis and/or Secondary Progressive Multiple Sclerosis.

5. Cladribine for use according to claim 1, 2, 3 and/or 4, wherein said progressive form of Multiple Sclerosis is Primary Progressive Multiple Sclerosis.

6. Cladribine for use according to claim 1, 2, 3 and/or 4, wherein said progressive form of Multiple Sclerosis is Secondary Progressive Multiple Sclerosis.

7. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to patients having an age between 18 and 65 years.

8. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to patients having an age between 18 and 51

years.

9. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to patients having an age between 12 and 51 years.

10. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to patients of female gender and/or to patients of male gender.

11. Cladribine for use according to one or more of the preceding claims, wherein said Patient has High Disease Activity (HDA) and/or has been diagnosed High Disease Activity.

12. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to patients being treatment naïve to Cladribine and/or disease modifying drugs other than Cladribine.

13. Cladribine for use according to one or more of claims 1 to 11, wherein said Cladribine is to be orally administered to patients who previously received Cladribine and/or disease modifying drugs other than Cladribine.

14. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to patients also receiving one or more disease modifying drugs other than Cladribine.

15. Cladribine for use according to one or more of claims 12-14, wherein said disease modifying drugs other than Cladribine are selected from the group consisting of:
Interferon beta-1a, Beta interferon-1a (e.g. Avonex®, Rebif®),
Interferon beta-1b, Beta interferon-1b (e.g. Betaferon®, Extavia®),

Peginterferon beta 1a (e.g. Plegridy®),
Alemtuzumab (e.g. Lemtrada®),
Daclizumab (e.g. Zinbryta®),
Dimethyl fumarate (e.g. Tecfidera®),
Fingolimod (e.g. Gilenya®),
Glatiramer acetate (e.g. Copaxone®),
Natalizumab (e.g. Tysabri®), and
Teriflunomide (e.g. Aubagio®).

16. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to each patient at fixed dose per patient, per body weight and per treatment year, wherein said fixed dose is selected from the range of 1.5 mg/kg to 4.0 mg/kg, preferably selected from the range of 1.5 mg/kg to 2.0 mg/kg, and especially is 1.75 mg/kg per treatment year with a maximum deviation of +/- 0.2 mg/kg,
and wherein the said fixed dose is to be orally administered to said patient within two adjacent months within said treatment year.

17. Cladribine for use according to claim 16, wherein said fixed dose is to be orally administered to said patient within two adjacent months starting at the beginning of said treatment year.

18. Cladribine for use according to claim 16 and/or 17, wherein said fixed dose is to be orally administered to said patient within one week or two weeks, preferably two adjacent weeks, of each of said two adjacent months.

19. Cladribine for use according to claim 16, 17 and/or 18, wherein said fixed dose is to be orally administered to said patient within one week or two adjacent weeks located at the beginning of each one of said two adjacent months.

20. Cladribine for use according to claim 16, 17, 18 and/or 19, wherein said fixed dose is to be orally administered to said patient, preferably divided into the respective amount of daily doses, within 2 to 7 days during said week, or within 2 to 7 days of each of said weeks.

21. Cladribine for use according to claim 16, 17, 18, 19 and/or 20, wherein said fixed dose
is to be orally administered to said patient, preferably divided into the respective amount of daily doses, within 2 to 7 days during said week, or within 2 to 7 days of each of said weeks.

22. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to each patient at said fixed dose per patient, per body weight and per treatment year, preferably as described in the claims above and/or below, and wherein the treatment comprises one or more additional treatment years.

23. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to each patient as said fixed dose per patient, per body weight and per treatment year, preferably as described in the claims above and/or below, and wherein the treatment comprises two treatment years, preferably two substantially identical treatment years.

24. Cladribine for use according to claim 20 and/or 21, wherein two of said treatment years are either directly adjacent to each other, or are separated by a gap 1 to 10 months.

25. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to each patient at a fixed dose per patient, per body weight and per treatment year,

a) wherein said fixed dose per treatment year is selected from the range of 1.5 mg/kg to 4.0 mg/kg, preferably selected from the range of 1.5 mg/kg to 2.0 mg/kg, and especially is 1.75 mg/kg per treatment year with a maximum deviation of +/- 0.2 mg/kg,

b) wherein said treatment year comprises:

(i) a treatment period of 2 months at the beginning of said treatment year, wherein said fixed dose of Cladribine is to be orally administered on about 1 to about 7 days each month, preferably on about 1 to about 7 days each month at the beginning of each month, said fixed dose being divided into daily doses of 5 to 20 mg of Cladribine,

(ii) a Cladribine-free period lasting 10 months, during which no Cladribine is to be administered.

26. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered to each patient at a fixed dose per patient, per body weight and per treatment year,

a) wherein said fixed dose per treatment year is selected from the range of 1.5 mg/kg to 4.0 mg/kg, preferably selected from the range of 1.5 mg/kg to 2.0 mg/kg, and especially is 1.75 mg/kg per treatment year with a maximum deviation of +/- 0.2 mg/kg,

b) wherein said treatment year comprises:

(iii) a treatment period of 2 months at the beginning of said treatment year, wherein said fixed dose of Cladribine is to be orally administered on 3 to 5 days each month at the beginning of each month, said fixed dose being divided into daily doses of 10 or 20 mg of Cladribine,

(iv) a Cladribine-free period lasting 10 months, during which no Cladribine is to be administered.

27. Cladribine for use according to one or more of the preceding claims, wherein said oral treatment of patients suffering from Primary Progressive Multiple Sclerosis and/or patients suffering from Secondary Progressive Multiple Sclerosis, wherein said Cladribine is to be orally administered to each patient at fixed dose per patient, per body weight and per treatment year, wherein said fixed dose per patient is 1.75 mg/kg per treatment year with a maximum deviation of +/- 0.2 mg/kg, and wherein said treatment comprises at least two treatment years, preferably two treatment years.

28. Cladribine for use according to one or more of the preceding claims, wherein the treatment comprises two treatment years that are substantially adjacent to either each other, or that are separated by a gap of 1 to 10 months, preferably 1 to 6 months.

29. Cladribine for use according to one or more of the preceding claims, wherein the treatment additionally comprises a subsequent treatment year,

a) wherein said fixed dose per treatment year is selected from the range of 0.75 mg/kg to 2.0 mg/kg, preferably selected from the range of 1.0 mg/kg to 1.5 mg/kg, and especially is 0.8 mg/kg per treatment year with a maximum deviation of +/- 0.2 mg/kg,

b) wherein said subsequent treatment year comprises:

(v) a treatment period of 1 month or 2 months at the beginning of said treatment year, wherein said fixed dose of Cladribine is to be orally administered on 3 to 5 days each month at the beginning of each month, said fixed dose being divided into daily doses of 10 or 20 mg of Cladribine,

(vi) a Cladribine-free period lasting 11 or 10 months respectively, during which no Cladribine is administered.

30. Cladribine for use according to one or more of the preceding claims, wherein the treatment comprises one or two treatment years as described in the claims above and/or below, optionally plus an additional subsequent treatment year as described in claim 26 or 29, followed by at least one year, preferably at least 2 years, in which no Cladribine is administered to said patients.

31. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered as a liquid, a tablet, or a capsule.

32. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered as a tablet, preferably a tablet comprising about 10 mg of Cladribine.

33. Cladribine for use according to one or more of the preceding claims, wherein said Cladribine is to be orally administered as a tablet comprising 10 mg of Cladribine in the form of a mixture of Cladribine, 2-hydroxypropyl-β-cyclodextrin and Cladribine-2-hydroxypropyl-β-cyclodextrin-complexes, wherein the weight ratio of Cladribine to 2-hydroxypropyl-β-cyclodextrin is between about 1:10 to about 1:16, preferably between 1:13 to 1:15.

34. Use of cladribine for the preparation of an oral pharmaceutical formulation for the treatment of progressive forms of Multiple Sclerosis, wherein
a cumulative dose of Cladribine of about 3.5 mg/kg body weight, with a maximum deviation of +/- 0.4 mg/kg, over 2 years, is to be administered as 1 treatment course of about 1.75 mg/kg +/- 0.2 mg/kg per year, wherein each treatment course consists of 2 treatment weeks, one at the beginning of the first month and one at the

beginning of the second month of the respective treatment year.

35. Use according to claim 34, wherein each treatment week consists of 4 or 5 days on which 10 mg or 20 mg of Cladribine for oral administration are to be administered, preferably as a single daily dose, depending on the body weight of the respective patient.

36. Use according to claim 35, wherein said 10 mg or 20 mg of Cladribine of said oral pharmaceutical formulation are to be administered as a tablet or capsule, preferably a tablet or capsule containing 10 mg of Cladribine.

37. Use according to claim 36, wherein said oral pharmaceutical formulation of 10 mg or 20 mg of Cladribine are to be administered as a tablet or capsule comprising 10 mg of Cladribine in the form of a mixture of Cladribine, 2-hydroxypropyl-β-cyclodextrin and Cladribine-2-hydroxypropyl-β-cyclodextrin-complexes, wherein the weight ratio of Cladribine to 2-hydroxypropyl-β-cyclodextrin is between about 1:10 to about 1:16, preferably between 1:13 to 1:15.

38. Use according to one or more of claims 34 to 37, wherein the progressive form of Multiple Sclerosis is Primary Progressive Multiple Sclerosis.

39. Use according to one or more of claims 34 to 37, wherein the progressive form of Multiple Sclerosis is Secondary Progressive Multiple Sclerosis.

40. Use according to one or more of claims 34 to 37, where the progressive form of Multiple Sclerosis is selected from the group consisting of Primary Progressive Multiple Sclerosis and Secondary Progressive Multiple Sclerosis, and wherein said oral pharmaceutical formulation is to be
orally administered at a cumulative dose of Cladribine of about 3.5 mg/kg body weight over 2 years, to be administered as 1 treatment course of about 1.75 mg/kg,

wherein each treatment course consists of 2 treatment weeks, one at the beginning of the first month and one at the beginning of the second month of the respective treatment year.

41. Use according to claim 40, wherein each treatment week consists of 4 or 5 days on which 10 mg or 20 mg of Cladribine is to be administered as said oral pharmaceutical formulation, preferably as a single daily dose, and preferably depending on the body weight of the respective patient.

42. Use according to one or more of the preceding claims for the treatment of patients that are between 18 and 65 years old.

43. Use according to one or more of the preceding claims for the treatment of patients that are between 18 and 51 years old.

44. Use according to one or more of the preceding claims for the treatment of patients that are between 12 and 51 years old.

45. Use according to one or more of the preceding claims for the treatment of patients of female gender and/or patients of male gender.

46. Use according to one or more of the preceding claims for the treatment of patients that are treatment naïve to Cladribine and/or disease modifying drugs other than Cladribine.

47. Use according to one or more of the preceding claims for the treatment of patients who previously received Cladribine and/or disease modifying drugs other than Cladribine.

48. Use according to one or more of the preceding claims for the treatment of patients that additionally receive one or more disease modifying drugs other than Cladribine.

49. Use according to one or more of the preceding claims, wherein said disease modifying drugs other than Cladribine are selected from the group consisting of:
Interferon beta-1a, Beta interferon-1a (e.g. Avonex®, Rebif®),
Interferon beta-1b, Beta interferon-1b (e.g. Betaferon®, Extavia®),
Peginterferon beta 1a (e.g. Plegridy®),
Alemtuzumab (e.g. Lemtrada®),
Daclizumab (e.g. Zinbryta®),
Dimethyl fumarate (e.g. Tecfidera®),
Fingolimod (e.g. Gilenya®),
Glatiramer acetate (e.g. Copaxone®),
Natalizumab (e.g. Tysabri®), and
Teriflunomide (e.g. Aubagio®).

50. Use according to one or more of the preceding claims, wherein after the completion of said 2 years with said 2 treatment courses, no Cladribine is administered to the patients in the subsequent 1 or 2 years following the completion of said 2 years with said 2 treatment courses.

51. Use according to one or more of the preceding claims, wherein to the patients having completed said 2 treatment courses of one year each, no further Cladribine treatment is required and/or administered administered to said patients in the subsequent years 3 and 4.

52. Use of cladribine for the preparation of an oral pharmaceutical formulation for the treatment of progressive forms of Multiple Sclerosis, wherein said oral pharmaceutical formulation is to be orally administered as tablets or capsules containing about 10 mg of Cladribine each, wherein said tablets or capsules are to

be administered during a period called treatment year comprising the following regimen::

(i) a treatment course lasting 2 months, wherein Cladribine tablets or capsules are to be orally administered daily at a daily dose of 10 or 20 mg of Cladribine on 3 to up to 6 days each month, preferably on 4 or 5 days of each month, preferably in the 1st week of the respective month (each a treatment week);

(ii) followed by a Cladribine-free period lasting 10 months, preferably until the end of the 1st treatment year, wherein no Cladribine is administered to said patient;

wherein patients having a bodyweight

- in the range of 40 to less than 50 kg are to be administered

1) 4 tablets or capsules (40 mg of Cladribine) in the 1st treatment week of said treatment course,

2) 4 tablets or capsules (40 mg of Cladribine) in the 2nd treatment week of said treatment course,

- in the range of 50 to less than 60 kg are to be administered

1) 5 tablets or capsules (50 mg of Cladribine) in the 1st treatment week of said treatment course, respectively,

2) 5 tablets or capsules (50 mg of Cladribine) in the 2nd treatment week of said treatment course,

- in the range of 60 to less than 70 kg are to be administered

1) 6 tablets or capsules (60 mg of Cladribine) in the 1st treatment week of said treatment course,

2) 6 tablets or capsules (60 mg of Cladribine) in the 2nd treatment week of said treatment course,

- in the range of 70 to less than 80 kg are to be administered

1) 7 tablets or capsules (70 mg of Cladribine) in the 1st treatment week of said treatment course,

2) 7 tablets or capsules (70 mg of Cladribine) in the 2nd treatment week of said treatment course,

- in the range of 80 to less than 90 kg are to be administered

1) 8 tablets or capsules (80 mg of Cladribine) in the 1st treatment week of said treatment course,

2) 7 tablets or capsules (70 mg of Cladribine) in the 2nd treatment week of said treatment course,

- in the range of 90 to less than 100 kg are to be administered

1) 9 tablets or capsules (90 mg of Cladribine) in the 1st treatment week of said treatment course,

2) 8 tablets or capsules (80 mg of Cladribine) in the 2nd treatment week of said treatment course,

- in the range of 100 to less than 110 kg are to be administered

1) 10 tablets or capsules (100 mg of Cladribine) in the 1st treatment week of said treatment course,

2) 9 tablets or capsules (90 mg of Cladribine) in the 2nd treatment week of said treatment course,

- in the range of 110 kg and above are to be administered

1) 10 tablets or capsules (100 mg of Cladribine) in the 1st treatment week of said treatment course,

2) 10 tablets or capsules (100 mg of Cladribine) in the 2nd treatment week of said treatment course.

53. Use according to claim 52, wherein said oral pharmaceutical formulation is to be administered for least one subsequent period called additional treatment year, wherein said additional treatment year is substantially identical, or preferably identical, to said regimen called treatment year.

54. Use according to claim 53, wherein said additional treatment year is directly adjacent to said regimen called treatment year, or there is gap of 1 to 10 months in

between the two treatment years.

55. Use according to claim 52 or 53, wherein said oral pharmaceutical formulation is to be administered for more than one subsequent periods called additional treatment year, preferably two additional treatment years, wherein all said additional treatment years are substantially identical, or preferably identical, and wherein said additional treatment years are directly adjacent to each other, or there is gap of 1 to 10 months in between at least two of said additional treatment years.

56. Use of cladribine for the preparation of an oral pharmaceutical formulation for the treatment of progressive forms of Multiple Sclerosis, wherein said oral pharmaceutical formulation is to be orally administered to said patient as tablets or capsules containing about 10 mg of Cladribine each, wherein said tablets or capsules are to be administered during a period called treatment year according comprising the following regimen:

(i) a first treatment course lasting 2 months, wherein Cladribine tablets or capsules are to be orally administered daily at a daily dose of 10 or 20 mg of Cladribine on 3 to up to 6 days each month, preferably on 4 or 5 days of each month, preferably in the 1st week of the respective month (treatment week);

(ii) followed by a first Cladribine-free period lasting 10 months, preferably until the end of a first treatment year, wherein no Cladribine is to be administered to said patient;

(iii) followed by a second treatment course lasting 2 months, wherein Cladribine tablets or capsules are to be orally administered daily at a daily dose of 10 or 20 mg of Cladribine on 3 to up to 6 days each month, preferably on 4 or 5 days of each month, preferably in the 1st week of the respective month (treatment week); and

(iv) followed by a second Cladribine-free period lasting 10 months, preferably until the end of a second treatment year, wherein no Cladribine is to be administered to said patient, and

wherein patients having a bodyweight

- in the range of 40 to less than 50 kg are to be administered

1) 4 tablets or capsules (40 mg of Cladribine) in the 1st treatment week of both the 1st and the 2nd treatment course, respectively,

2) 4 tablets or capsules (40 mg of Cladribine) in the 2nd treatment week of both the 1st and the 2nd treatment course, respectively,

- in the range of 50 to less than 60 kg are to be administered

1) 5 tablets or capsules (50 mg of Cladribine) in the 1st treatment week of both the 1st and the 2nd treatment course, respectively,

2) 5 tablets or capsules (50 mg of Cladribine) in the 2nd treatment week of both the 1st and the 2nd treatment course, respectively,

- in the range of 60 to less than 70 kg are to be administered

1) 6 tablets or capsules (60 mg of Cladribine) in the 1st treatment week of both the 1st and the 2nd treatment course, respectively,

2) 6 tablets or capsules (60 mg of Cladribine) in the 2nd treatment week of both the 1st and the 2nd treatment course, respectively,

- in the range of 70 to less than 80 kg are to be administered

1) 7 tablets or capsules (70 mg of Cladribine) in the 1st treatment week of both the 1st and the 2nd treatment course, respectively,

2) 7 tablets or capsules (70 mg of Cladribine) in the 2nd treatment week of both the 1st and the 2nd treatment course, respectively,

- in the range of 80 to less than 90 kg are to be administered

1) 8 tablets or capsules (80 mg of Cladribine) in the 1st treatment week of both the 1st and the 2nd treatment course, respectively,

2) 7 tablets or capsules (70 mg of Cladribine) in the 2nd treatment week of both the 1st and the 2nd treatment course, respectively,

- in the range of 90 to less than 100 kg are to be administered

1) 9 tablets or capsules (90 mg of Cladribine) in the 1st treatment week of both the 1st and the 2nd treatment course, respectively,

2) 8 tablets or capsules (80 mg of Cladribine) in the 2nd treatment week of both the

1st and the 2nd treatment course, respectively,

- in the range of 100 to less than 110 kg are to be administered

1) 10 tablets or capsules (100 mg of Cladribine) in the 1st treatment week of both the 1st and the 2nd treatment course, respectively,

2) 9 tablets or capsules (90 mg of Cladribine) in the 2nd treatment week of both the 1st and the 2nd treatment course, respectively,

- in the range of 110 kg and above are to be administered

1) 10 tablets or capsules (100 mg of Cladribine) in the 1st treatment week of both the 1st and the 2nd treatment course, respectively,

2) 10 tablets or capsules (100 mg of Cladribine) in the 2nd treatment week of both the 1st and the 2nd treatment course, respectively.

57. Use according one or more of the preceding claims, wherein said 10 mg or 20 mg of Cladribine for oral administration are to be administered to the patient as a tablet or capsule comprising 10 mg of Cladribine in the form of a mixture of Cladribine, 2-hydroxypropyl-β-cyclodextrin and Cladribine-2-hydroxypropyl-β-cyclodextrin-complexes, wherein the weight ratio of Cladribine to 2-hydroxypropyl-β-cyclodextrin is between about 1:10 to about 1:16, preferably between 1:13 to 1:15.

58. Use according to one or more of the preceding claims, wherein the progressive form of Multiple Sclerosis is Primary Progressive Multiple Sclerosis.

59. Use according to one or more of the preceding claims, wherein the progressive form of Multiple Sclerosis is Secondary Progressive Multiple Sclerosis.

60. Use according to one or more of the preceding claims for the treatment of patients that are between 18 and 51 years or 12 and 51 years old.

61. Use according to one or more of the preceding claims, wherein the patients to be treated are patients of female gender and/or patients of male gender.

62. Use according to one or more of the preceding claims, wherein the patients to be treated are treatment naïve to Cladribine and/or disease modifying drugs other than Cladribine.

63. Use according to one or more of the preceding claims, wherein the patients are patients who previously received Cladribine and/or disease modifying drugs other than Cladribine.

64. Use according to one or more of the preceding claims, wherein the patients to be treated additionally receive one or more disease modifying drugs other than Cladribine.

65. Use according to one or more of the preceding claims, wherein said disease modifying drugs other than Cladribine are selected from the group consisting of:
Interferon beta-1a, Beta interferon-1a (e.g. Avonex®, Rebif®),
Interferon beta-1b, Beta interferon-1b (e.g. Betaferon®, Extavia®),
Peginterferon beta 1a (e.g. Plegridy®),
Alemtuzumab (e.g. Lemtrada®),
Daclizumab (e.g. Zinbryta®),
Dimethyl fumarate (e.g. Tecfidera®),
Fingolimod (e.g. Gilenya®),
Glatiramer acetate (e.g. Copaxone®),
Natalizumab (e.g. Tysabri®), and
Teriflunomide (e.g. Aubagio®).

66. Use according to one or more of the preceding claims, wherein after the completion of said 2 years with said 2 treatment courses, no Cladribine is to be administered to

the patients in the subsequent 1 or 2 years following the completion of said 2 years with said 2 treatment courses.

67. Use according to one or more of the preceding claims, wherein to the patients having completed said 2 treatment courses of one year each, no further Cladribine treatment is required and/or to be administered to said patients in the subsequent years 3 and 4.

68. Use according to one or more of the preceding claims, wherein to the patients to be treated have been diagnosed to suffer from progressive forms Multiple Sclerosis, preferably selected from the group consisting of Primary Progressive Multiple Sclerosis and Secondary Progressive Multiple Sclerosis, preferably before the start of treatment according to the method.

69. Use according to one or more of the preceding claims, wherein to the patients to be treated have been diagnosed Primary Progressive Multiple Sclerosis, preferably before the start of treatment according to the method.

70. Use according to one or more of the preceding claims, wherein to the patients to be treated have been diagnosed Secondary Progressive Multiple Sclerosis, preferably before the start of treatment according to the method.

71. Use according to one or more of the preceding claims, wherein said Patient has High Disease Activity (HDA) and/or has been diagnosed High Disease Activity.