Claims:

1. Use of Cladribine for the manufacture of a medicament for oral use for treating a progressive form of Multiple Sclerosis, wherein said medicament is to be orally administered to a patient at fixed dose per patient, per body weight and per treatment year, wherein said medicament is to be administered in a manner that said fixed dose of Cladribine per patient is 1.75 mg/kg per treatment year with a maximum deviation of +/- 0.2 mg/kg ~~is in a range of 1.5 mg/kg to 4.0 mg/kg~~, wherein the progressive form of Multiple Sclerosis is ~~selected from the group consisting of~~ Secondary Progressive Multiple Sclerosis (SPMS), ~~Primary Progressive Multiple Sclerosis (PPMS), and Progressive Relapsing Multiple Sclerosis (PRMS),~~ and wherein the progressive form of Multiple Sclerosis does not include Early Secondary Progressive Multiple Sclerosis (ESPMS).

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

~~3. The use according to claim 1 or claim 2, wherein said progressive form of multiple sclerosis comprises Primary Progressive Multiple Sclerosis and/or Secondary Progressive Multiple Sclerosis.~~

~~4~~2. The use according to ~~any one of~~ claim~~s~~ 1~~, 2 and/or 3~~, wherein said fixed dose is to be orally administered to said patient within two adjacent months within said treatment year.

3~~5~~. The use according to claim 2~~4~~, wherein said fixed dose is to be orally administered to said patient within one week or two adjacent weeks at the beginning of each one of said two adjacent months.

4~~6~~. The use according to claim 3~~5~~, wherein said fixed dose is to be orally administered to said patient within 4 to 5 days during said week, or within 4 to 5 days of each of said weeks.

5~~7~~. The use according to any one of claims 1 to 4~~6~~, wherein said Cladribine is to be orally administered for at least three treatment years.

6~~8~~. The use according to any one of claims 1 to 5~~7~~, wherein each 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 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, and

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

7~~9~~. The use according to any one of claims 1 to 6~~8~~, wherein said patient suffers from ~~Primary Progressive Multiple Sclerosis and/or from~~ Secondary Progressive Multiple Sclerosis, 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 orally administering Cladribine comprises at least two treatment years.

8~~10~~. The use according to any one of claims 1 to 7~~9~~, wherein said ~~orally administering~~ Cladribine is to be orally administered during~~comprises~~ at least three treatment years,

a) wherein said fixed dose per treatment year is ~~from 0.75 mg/kg to 2.0 mg/kg~~1.75 mg/kg per treatment year with a maximum deviation of +/- 0.2 mg/kg,

b) wherein the third treatment year comprises:

(i) 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, and

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

9~~11~~. The use according to any one of claims 1 to 8~~10~~, wherein ~~orally administering~~ Cladribine ~~is~~ is to be orally administered during ~~in~~ one or two treatment years, optionally plus ~~an~~ one additional subsequent treatment year, followed by at least one year in which no Cladribine is to be administered to said patient.

10~~12~~. The use according to any one of claims 1 to 9~~11~~, wherein said medicament containing Cladribine is to be orally administered as a liquid, a tablet, or a capsule.

11~~13~~. The use according to any one of claims 1 to 10~~2~~, wherein said medicament containing 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 1:10 to 1:16.

12~~14~~. Use of Cladribine for the manufacture of a medicament for oral use for treating a patient diagnosed as suffering from a progressive form of Multiple Sclerosis, wherein said medicament is to be orally administered to a patient comprising the following:

~~orally administering to said patient~~ 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 in each year 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,

wherein the progressive form of Multiple Sclerosis is ~~selected from the group consisting of~~ Secondary Progressive Multiple Sclerosis (SPMS~~), Primary Progressive Multiple Sclerosis (PPMS), and Progressive Relapsing Multiple Sclerosis (PRMS)~~, and wherein the progressive form of Multiple Sclerosis does not include Early Secondary Progressive Multiple Sclerosis (ESPMS).

13~~15~~. The use according to claim 12~~4~~, wherein each treatment week consists of 4 or 5 days on which said patient is to receive~~s~~ 10 mg or 20 mg of Cladribine for oral administration, depending on the body weight of the patient.

14~~16~~. The use according to claim 13~~5~~, wherein said patient is to receive~~s~~ the 10 mg or 20 mg of Cladribine for oral administration as a tablet or capsule.

15~~17~~. The use according to claim 1~~46~~, wherein said patient is to receive~~s~~ the 10 mg or 20 mg of Cladribine for oral administration 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 1:10 to 1:16.

16~~18~~. The use according to any one of claims 1~~2~~4 to 15~~17~~, where the progressive form of Multiple Sclerosis is ~~selected from the group consisting of Primary Progressive Multiple Sclerosis and~~ Secondary Progressive Multiple Sclerosis.

17~~19~~. The use according to any one of claims 1~~2~~4 to 1~~8~~6, wherein each treatment week consists of 4 or 5 days on which said patient is to receive~~s~~ 10 mg or 20 mg of Cladribine for oral administration.

18~~20~~. The use according to any one of claims 1~~2~~4 to 17~~19~~, wherein said patient is between 18 and 65 years old.

19~~21~~. The use according to any one of claims 1~~2~~4 to 18~~20~~, wherein the patient additionally is to receive~~s~~ at least one disease modifying drug other than Cladribine.

20~~22~~. The use according to any one of claims 1~~2~~4 to 19~~21~~, wherein said at least one disease modifying drug other than Cladribine is an interferon selected from the group consisting of: Interferon beta-1a, Beta interferon-1a, Interferon beta-1b, Beta interferon-1b, and Peginterferon beta 1a.

21~~23~~. The use according to any one of claims 1~~4~~2 to 20~~2~~, 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.

22~~24~~. Use of Cladribine for the manufacture of a medicament for oral use for treating a patient suffering from a progressive form of Multiple Sclerosis, wherein said medicament 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 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 a treatment week of from 3 to up to 6 days each month;

(ii) followed by a Cladribine-free period lasting 10 months wherein no Cladribine is to be 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; or

-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.

23~~25~~. The use according to claim 22~~4~~, wherein the treatment further comprises at least one subsequent additional treatment year, wherein said additional treatment year is substantially identical to said treatment year.

24~~26~~. The use according to claim 22~~4~~ or 2~~5~~3, wherein said additional treatment year is directly adjacent to said treatment year, or wherein there is a gap of 1 to 10 months in between the two treatment years.

25~~27~~. Use of Cladribine for the manufacture of a medicament for oral use in treating a patient suffering from a progressive form of Multiple Sclerosis, wherein the progressive form of Multiple Sclerosis is ~~selected from the group consisting of~~ Secondary Progressive Multiple Sclerosis (SPMS), ~~Primary Progressive Multiple Sclerosis (PPMS), and Progressive Relapsing Multiple Sclerosis (PRMS),~~ and wherein the progressive form of Multiple Sclerosis does not include Early Secondary Progressive Multiple Sclerosis (ESPMS), said medicament is provided in form tablets or capsules containing about 10 mg of Cladribine each, wherein said tablets or capsules are to be administered during two treatment years 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;

(ii) followed by a first Cladribine-free period lasting 10 months, 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; and

(iv) followed by a second Cladribine-free period lasting 10 months, 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; or

-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.

2628. The use according to claim 275, 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 1:10 to 1:16.

~~29. The use according to claim 27 or 28, wherein the progressive form of Multiple Sclerosis is Primary Progressive Multiple Sclerosis.~~

2730. The use according to claim 275 or 268, wherein the progressive form of Multiple Sclerosis is Secondary Progressive Multiple Sclerosis.

2831. The use according to claim 2725, 28 26 and/or 297, wherein the patient additionally is to receives at least one disease modifying drug other than Cladribine.

2932. The use according to claim 3128, wherein said at least one disease modifying drug other than Cladribine is an interferon selected from the group consisting of: Interferon beta-1a, Beta interferon-1a, Interferon beta-1b, Beta interferon-1b, and Peginterferon beta 1a.

3033. The use according to any one of claims 27 to 3229, wherein to the patients having completed said 2 treatment courses of one year each, no further Cladribine treatment is to be administered to said patients in the subsequent years 3 and 4.

3134. The use according to any one of claims ~~27~~ 26 to ~~33~~30, wherein the progressive form of Multiple Sclerosis is ~~selected from the group consisting of Primary Progressive Multiple Sclerosis and~~ Secondary Progressive Multiple Sclerosis.