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Cladribine Tablets Use in People with Multiple Sclerosis up to 4 Years and Beyond Following Treatment Initiation: Results From Multi-Country Patient Support Programmes

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RESEARCH IN CONTEXT

1. **Among people with MS with ≥4 years' follow-up from treatment initiation, only a small proportion (1.8–5.6%) received additional cladribine tablets treatment.**
2. **Nurse-pharmacy-led patient support programmes across the globe enable valuable data collection and may improve Year 2 treatment adherence to cladribine tablets in accordance with local product labels.**

OBJECTIVES

To examine data from patient support programmes (PSPs) from specific world regions* on:

- **Initiation and completion of the full 2-yearly short courses of cladribine tablets**
- **The proportion of people with multiple sclerosis (PwMS) who initiated additional cladribine tablets treatment**

***See Figure 1 for the complete list of countries included.**

INTRODUCTION

The nurse-pharmacy-led PSPs adveva® (worldwide), MS LifeLines® (United States), and Alcura Healthcare (The Netherlands), upon signed patient consent, collect clinical information on people with multiple sclerosis (PwMS) receiving cladribine tablets (3.5 mg/kg cumulative dose over 2 years, then a 2-year treatment-free period per product label). As of July 2024, and since EU approval, the cumulative exposure to cladribine tablets in the post-approval setting is >101,000 patients (data on file, Merck).

Data extracted from PSPs can provide information on the completion of treatment with cladribine tablets and if/when additional treatment is initiated.

METHODS

- Data extracted from the PSPs from **05 December 2017–01 December 2023.**
- PwMS were followed from treatment initiation (i.e., baseline: Day 1 of Course 1) until the cut-off date, loss to follow-up or treatment discontinuation, whichever came first.
- Prior use of disease-modifying therapy (DMT), initiation and completion of the full 2-year course of cladribine tablets, and time to initiation of Year 2 of treatment (among PwMS with ≥18 months' follow-up since treatment initiation) were reported.
- Individuals with ≥4 years' follow-up since treatment initiation who received additional cladribine tablets treatment at or after 4 years were also captured.

RESULTS

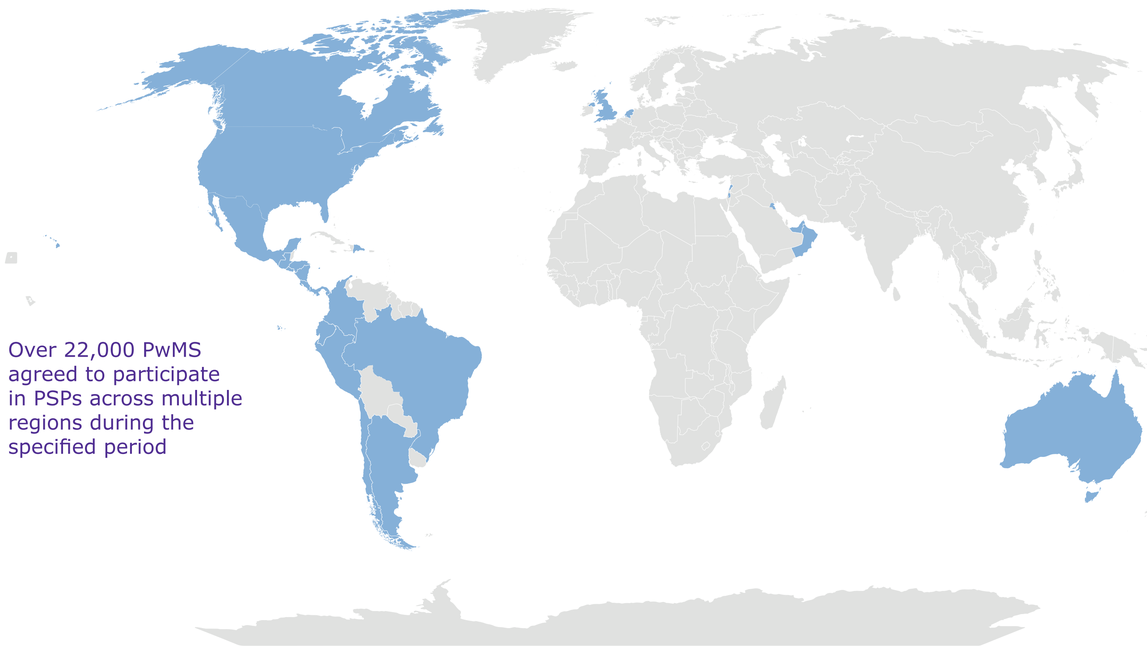
Figure 1. Regions Covered By PSPs and PwMS Demographics

Participants N=22,082

Female participants (range), 70.9–81.3%

Mean (SD) age (range), 34.2 (9.7)–49.1 (12.1) years

Prior DMT use* (range), 30.0–100%



Regions included: Australia, Canada, Gulf region (Bahrain, Kuwait, Oman, United Arab Emirates), Latin America countries (Argentina, Chile, Colombia, Brazil, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, and Peru), Near East countries (Lebanon and Palestine), the Netherlands, United Kingdom, and the United States.
*Data from Australia did not contribute to the analysis. DMT, disease-modifying therapy; PSP, patient support programme; SD, standard deviation

Figure 2. Most Recent DMT Use Prior to Cladribine Tablet Initiation

UK data not available

DMT, disease-modifying therapy; Lat Am, Latin America; NL, Netherlands, PwMS, people with multiple sclerosis; UK, United Kingdom; US, United States

- Most treatment-experienced PwMS had ≥1 prior DMT with the most common being oral DMTs.

Table 1. Clinical and Demographic Characteristics of PwMS

Country (N)	Australia (799)	Canada (3665)	Gulf (258)	Lat Am (1854)	Near East (75)	NL (681)	UK (2320)	US (12,418)
BASELINE DEMOGRAPHICS								
Female, n (%)	648 (81.3)	2781 (76.5)	190 (73.6)	1334 (72.0)	61 (70.9)	NA	1777 (76.7)	9113 (74.8)
Age in years at cladribine tablets initiation, mean (SD)	49.1 (12.1)	44.1 (10.6)	35.4 (8.8)	36.3 (10.4)	34.2 (9.7)	NA	NA	48.5 (12.1)
DMT TREATMENT PRIOR TO CLADRIBINE TABLETS, N (%)*								
Treatment-naïve	31 (3.9)	0 (0)	122 (47.3)	784 (42.3)	12 (14.0)	102 (15.0)	1548 (66.7)	6 (<0.1)
Treatment-experienced	73 (9.1)	3665 (100)	136 (52.7)	1070 (57.7)	65 (86.7)	554 (81.4)	696 (30.0)	9873 (79.5)
YEAR 2 TREATMENT								
Year 2 treatment initiation[a], n (%)	511/561 (91.1)	2727/2968 (91.9)	160/160 (100)	1004/1085 (92.5)	76/76 (100)	414/481 (86.1)	1758/1915 (91.8)	7748/9355 (82.8)
Mean (SD) time to Year 2 initiation, months	12.4 (3.8)	13.4 (2.6)	12.5 (1.4)	12.7 (1.4)	13.1 (3.0)	12.9 (1.9)	13.9 (3.5)	13.2 (2.7)
Year 2 treatment completion[b], n (%)	NA	2661/2727 (97.6)	158/160 (98.8)	977/1004 (97.3)	76/76 (100)	394/414 (95.2)	1719/1758 (97.8)	7251/7748 (93.6)
ADDITIONAL TREATMENT								
Additional treatment received after 24 months[c], n (%)	NE[d]	167/2248 (7.4)	2/125 (1.6)	23/167 (13.8)	NA	18/328 (5.5)	74/1410 (5.2)	NA
Additional treatment received after 48 months in PwMS with at least 48 month's follow-up, n/N (%)	NA	72/1294 (5.6)	NA	5/116 (4.3)	NA	5/133 (3.8)	14/766 (1.8)	NA

*Missing data excluded from the table. Start of study period in each country — Australia: 05 Dec 2017; Canada: 29 Nov 2017; Gulf: 25 Mar 2018; Lat Am: 02 May 2018; UK: 07 Sep 2017; US: 29 Mar 2019; Near East: 28 Apr 2019; Netherlands: 01 Nov 2017. [a]Among participants with ≥18 months of follow-up since Year 1 initiation. [b]Participants were followed from treatment initiation until the cut-off date, loss to follow-up or treatment discontinuation; [c]Among participants with ≥24 months of follow-up since Year 1 initiation or participants stopping treatment with cladribine tablets. [d]Not estimated because data on only one patient was available.
Lat Am, Latin America; NL, Netherlands; NA, not available; NE, not estimated; PSP, Patient Support Programme; PwMS, people with multiple sclerosis; SD, standard deviation; UK, United Kingdom; US, United States

- Overall, 22,070 PwMS (female [range]: 70.7%–81.3%; age [range]: 34–49.1 years) initiated cladribine tablets treatment during the specified period.
- In PwMS with ≥18 months' follow-up, ≥82.8% initiated Year 2 of cladribine tablets treatment with a mean time (standard deviation) to initiation of 12.4 (±3.8) to 13.9 (±3.5) months after starting the initial cladribine tablets treatment.
- At least 93.6% of PwMS completed Year 2 of cladribine tablets treatment.
- Median (SD) time to additional treatment initiation was only available for Latin America and the Netherlands, 45.9 (12.5) and 42.6 (9.9), respectively.
- Additional treatment was administered beyond 48 months in a small proportion of patients.
  - Data from PSPs in Canada, Latin America, the Netherlands, and the United Kingdom showed that 2309 PwMS had more than 48 months follow-up available. Among them, the proportion receiving additional treatment after 48 months was 5.6% in Canada, 4.3% in Latin America, 3.8% in the Netherlands, and 1.8% in the United Kingdom.

CONCLUSIONS

- **In PwMS with ≥18 months' follow-up, ≥82.8% initiated Year 2 of cladribine tablets treatment with a mean time to initiation of 12.4–13.9 months.**
- **Data from global PSPs demonstrate that the majority of PwMS completed the full 2-yearly short courses of cladribine tablets.**

SCAN FOR AFFILIATIONS, DISCLOSURES, AND SUPPLEMENTARY MATERIALS

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Supplementary Materials

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MK has nothing to declare.

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