High Adherence and Minimal Delays of Year 2 Treatment in People With Multiple Sclerosis Treated With Cladribine Tablets: Results From Multi-Country Patient Support Programmes

J. Oh[1], M. Ayer[2], R. Alroughani[3], C. Lemieux[4], K. Morgan[5], M. D'Eramo[6], T. Vella[7], A. Boshra[8], S. de Souza[9], E. Verdun di Cantogno[10], M. Sabidó[9]

[1]St Michael's Hospital, University of Toronto, Division of Neurology, Department of Medicine, Toronto, ON, Canada; [2]Southampton General Hospital, Southampton, UK; [3]Al-Amiri Hospital, Division of Neurology, Department of Medicine, Kuwait City, Kuwait; [4]EMD Serono, Inc., Mississauga, ON, Canada (an affiliate of Merck KGaA); [5]Merck Serono Ltd, Feltham, UK (an affiliate of Merck KGaA); [6]Merck S.A., Buenos Aires, Argentina (an affiliate of Merck KGaA); [7]Merck Healthcare Pty. Ltd, Macquarie Park, NSW, Australia (an affiliate of Merck KGaA); [8]Merck Serono Middle East FZ-Ltd, Dubai, United Arab Emirates (an affiliate of Merck KGaA); [9]Merck Healthcare KGaA, Darmstadt, Germany; [10]EMD Serono Research and Development Institute, Inc., Billerica, MA, USA (an affiliate of Merck KGaA)

CONCLUSIONS

Adherence to cladribine tablets at Year 2 was consistently high across participating countries with minimal delays in Year 2 treatment initiation

A small proportion of patients have received additional courses of cladribine tablets 24 months or more after initiating therapy

INTRODUCTION

- The recommended dose of cladribine tablets is 3.5 mg/kg cumulative over 2 years. This is provided by courses of 1.75 mg/kg administered at the start of Year 1 and Year 2, respectively
  - The European Medicines Agency (EMA) and Australian product labels state that no further cladribine treatment is required in Years 3 and 4, while the Canadian label states that patients should be observed for another 2 years
- Consequently, some people with multiple sclerosis (pwMS) can receive a further course of cladribine tablets after Year 2
- Adveva®, a multinational nurse-/pharmacy-led patient support programme (PSP), collects treatment-related clinical information for pwMS receiving cladribine tablets

OBJECTIVES

- **To use data from the Adveva® PSP to:**
  - **Evaluate the start, and delay in start, of Year 2 treatment based on local label guidance in Australia, Canada, the UK, and Gulf and Latin American (LatAm) countries***
  - **Describe the proportion of patients who initiated course 3 of cladribine tablets**

*Gulf includes Kuwait, Oman, and United Arab Emirates. LatAm countries include Argentina, Chile, Colombia, Costa Rica, the Dominican Republic, Ecuador, El Salvador, Honduras, Mexico, Nicaragua, Panama, and Peru.

METHODS

- Cladribine treatment-related clinical data collected from Adveva® between 05 December 2017 and 23 February 2022 were analysed
- PwMS were followed from treatment initiation with cladribine tablets until the cut-off date, loss to follow-up, or treatment discontinuation
- In countries with pwMS with ≥24 months' follow-up since Year 1 treatment initiation (Australia, Canada, and the UK), information on those who received subsequent treatment courses of cladribine tablets are also described

RESULTS

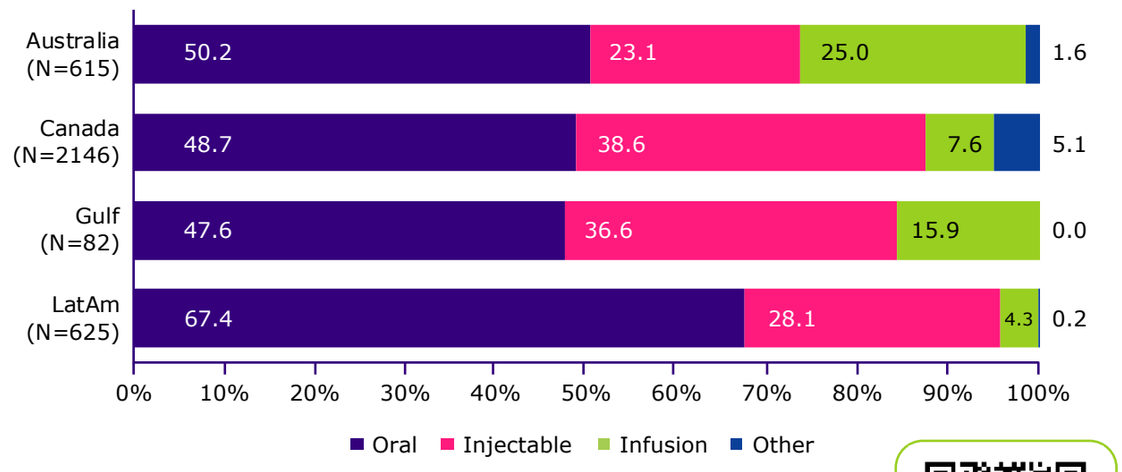
Table 1. Clinical Characteristics and Prior DMT Use in Patients Initiating Cladribine Tablets

	Australia (N=898)	Canada (N=2146)	Gulf (N=116)	LatAm (N=1010)	UK (N=1469)
Female, n (%)	702 (78.2)	1612 (75.6)	84 (72.4)	699 (69.2)	1110 (75.8)
Age in years at CladT initiation, mean (SD)	48.6 (12.1)	42.7 (10.3)	35.2 (9.0)	36.0 (10.0)	NA
DMT treatment prior to CladT, n (%)					
Missing value	46 (5.1)	0 (0)	0 (0)	0 (0)	118 (8.0)
Naïve to treatment	237 (26.4)	0 (0)	34 (29.3)	385 (38.1)	826 (61.1)
Prior DMT use	615 (68.5)	2146 (100)	82 (70.7)	625 (61.9)	525 (38.9)

CladT, cladribine tablets; **DMT**, disease-modifying therapy; **LatAm**, Latin America; **SD**, standard deviation

- Data for a total of 5649 patients initiating cladribine tablets were collected from Adveva®.
- Prior disease-modifying therapy (DMT) use in the PSP population varied by country (**Table 1**)
- Of the patients switching to cladribine tablets, the most common prior DMTs were oral therapies. The proportion of patients receiving prior oral treatment ranged from 47.6% in Gulf countries to 67.4% in LatAm countries (**Figure 1**)

Figure 1. Most Recent DMT Before Initiating Cladribine Tablets

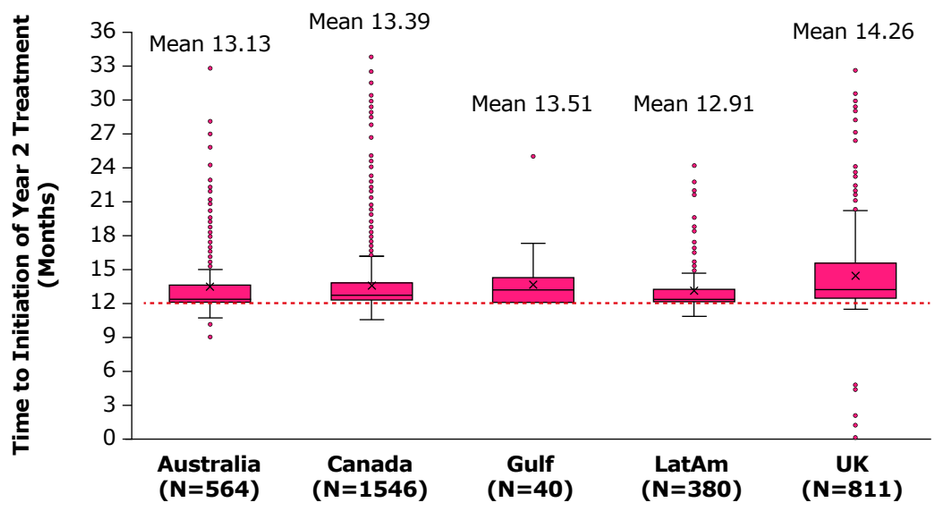


Data for the UK are not available.
DMT, disease-modifying therapy; **LatAm**, Latin America

- Among patients with at least 18 months of follow-up since Year 1 initiation, over 95% had initiated Year 2 of treatment
  - Australia: 97.2%; Canada: 95.8%; Gulf and LatAm: 100%; UK: 95.5%
- The median time to initiation of Year 2 treatment ranged from 12.16 to 13.14 months (**Figure 2**)

SCAN HERE FOR ADDITIONAL CONTENT

Figure 2. Time to Initiation of Year 2 Treatment With Cladribine Tablets, by Country



Data from patients with ≥18 months of history since initiating treatment in Year 1. 'x' indicates the mean value. Central line marks median; top and bottom of box marks Q3 and Q1, respectively; top and bottom points mark max and min, respectively. See Supplementary Table 1 for numerical values.
LatAm, Latin America; **SD**, standard deviation

Table 2. Course 3 Administration and Time to Course 3 Initiation Among Patients Initiating Cladribine Tablets

Course 3 initiation	Australia (N=898)	Canada (N=2146)	UK (N=1469)
Course 3 administration, among those with ≥24 months since Year 1 initiation[a], n (%)	11/142 (7.7)	14/219 (6.4)	3/656 (0.5)
Time to course 3 initiation since Year 1 initiation in months[a], mean (SD)	29.4 (4.3)	35.7 (6.7)	40.2 (3.9)

[a]Denominator includes patients with ≥24 months since initiation of Year 1 or patients stopping treatment with cladribine tablets.
SD, standard deviation

- Among those initiating Year 2 of treatment, a delay of 6 months or more occurred for 4.6% of patients in Australia, 4.3% of patients in Canada, 2.5% of patients in Gulf countries, 2.3% of patients in LatAm countries, and 10.3% of patients in the UK (**Supplementary Table 1**)
  - In the UK, the delay may be related to the Association of British Neurologists (ABN) COVID-19 guidelines, that were later revised
- Data on course 3 initiation was available from Australia, Canada, and the UK, and was initiated by 0.5–7.7% of patients in these countries (**Table 2**)
  - A third course of treatment following completion of treatment in Years 1 and 2 is not required according to the current product label in these countries
- Course 3 initiation was received on average between 29.4 and 40.2 months after Year 1 initiation (**Table 2**)

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