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Year 1 Performance of adveva[®], a Patient Support Program for Patients Taking Cladribine Tablets for Highly Active Relapsing Remitting Multiple Sclerosis in the United Kingdom

K. Morgan, N. Lott, M. Lyons

This analysis was sponsored by Merck Serono Ltd, a business of Merck KGaA, Darmstadt, Germany

The adveva[®] nurse-led service was provided by Lloyds Pharmacy Clinical Homecare.

KM and **NL** are employees of Merck Serono Ltd, a business of Merck KGaA, Darmstadt, Germany. **ML** is a former employee of Merck Serono Ltd and is a current employee of Roche Products Ltd.

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CONCLUSION

This is the first report in a post-approval and real world setting that suggests that the majority of patients find cladribine tablets simple-to-take.



100%

All 133 patients included in this assessment self-reported that they achieved the required cumulative 1.75 mg/kg dose of cladribine tablets in their first year of treatment.



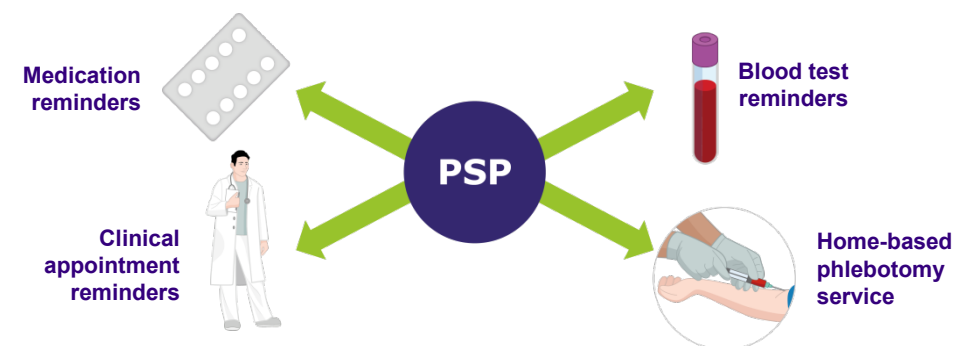
A proactive telephone-based patient support program was of particular value to the 22 (17%) of patients who required additional support during their treatment days.



INTRODUCTION

- Merck provides a free patient support program (PSP), called adveva[®], to support patients prescribed cladribine tablets to receive medication reminders during treatment days.
- The service also offers blood test reminders, a home-based phlebotomy service, and clinical appointment reminders (Figure 1).
- Adherence to disease-modifying therapy is a key determinant of treatment effectiveness, relating to drug regimen, patient knowledge, and patient-healthcare practitioner relationships.¹

Figure 1. Full Support Services of the PSP



OBJECTIVE

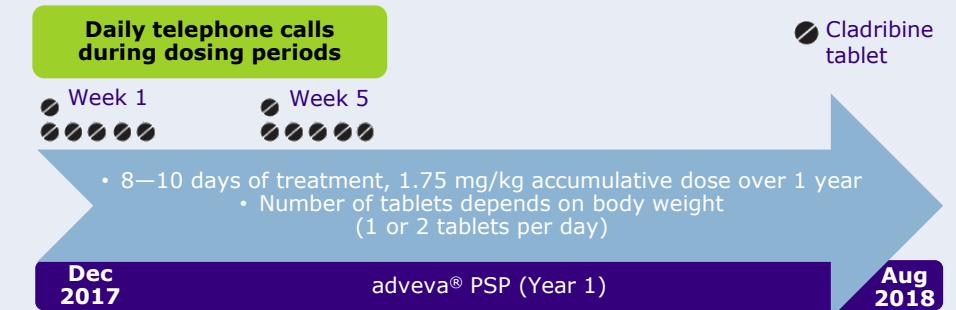
To present year 1 results of a PSP for patients with highly active relapsing-remitting multiple sclerosis (RRMS) taking cladribine tablets.



METHODS

- Aggregated and anonymized telephone conversation records were reviewed between December 2017 and August 2018 (Figure 2).
- The analysis determined whether patient-reported adherence, recorded within the PSP data collection system, was achieved and if basic support or additional support was required to achieve the full first year cladribine tablets cumulative dose of 1.75 mg/kg.
- All potential adverse events (AEs) are reported to Merck KGaA, the manufacturer, in accordance with local reporting timelines.

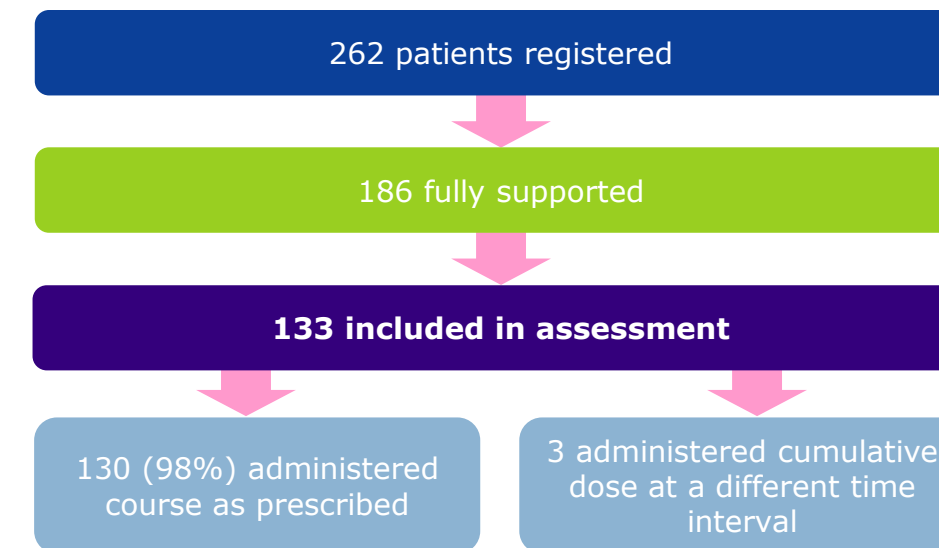
Figure 2. PSP Support Between Analysis Time Points



RESULTS

- 262 patients were registered with adveva[®] between December 2017 and August 2018 (Figure 3).
- Of these, 186 patients were registered as fully supported patients (daily phone calls on treatment days) (Figure 3).
- 133 patients who self-reported to have completed both treatment weeks in year 1 at the time of assessment (Figure 3); 53 patients had not yet reached week 5 at the time of assessment.

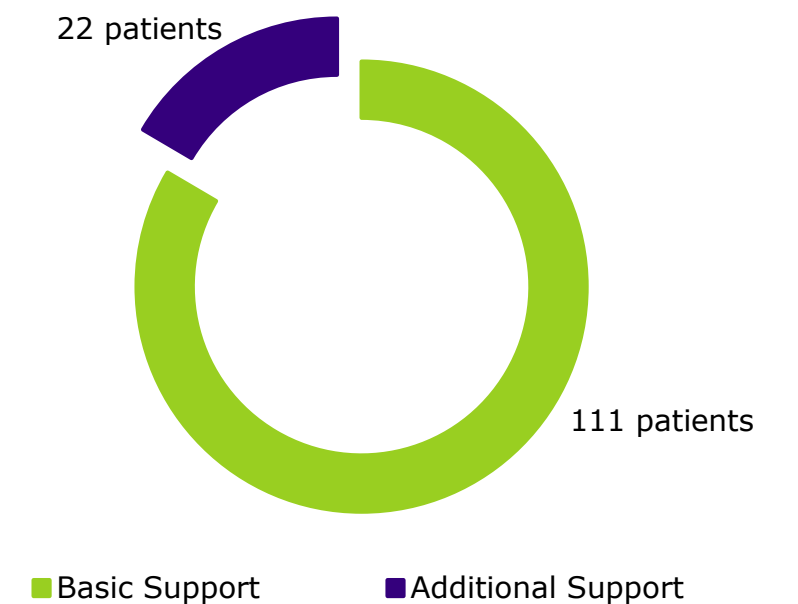
Figure 3. Patient Flow



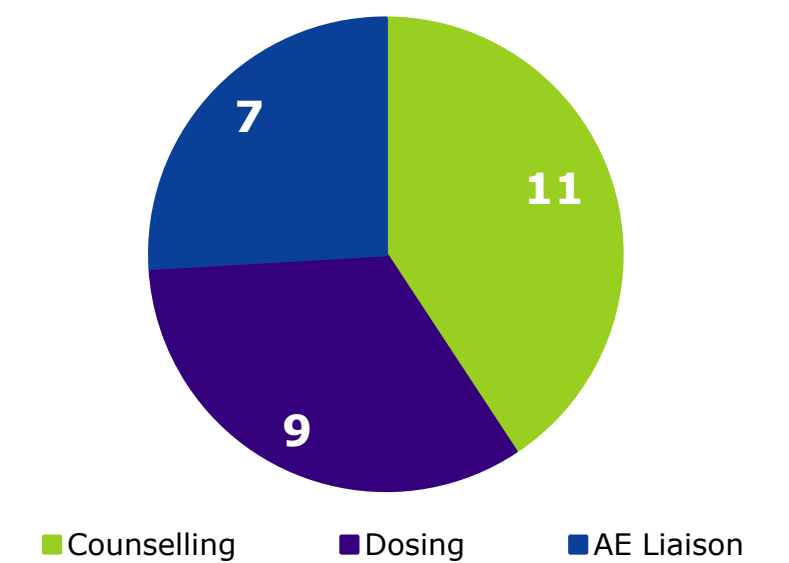
- 100% of patients analyzed successfully took the cumulative dose of 1.75 mg/kg in the first year.
 - Of the three patients who did not achieve this within the recommended time frame, one patient had a 1-day extension, one took the last dose 1 week late, and one administered the second treatment week 1 week early.
- 22 (17%) patients required additional support from the adveva[®] call handlers during their treatment days.
 - Discussion topics for these patients (may involve more than one topic) included: treatment counselling (to support patients using approved scripts) (41%), dosing advice (30%), and liaising over AEs (30%) (Figure 4).

Figure 4. Breakdown of Support Provided to Patients Enrolled on the PSP

Level of Support Patients Received



Reasons for Additional Support*



*While 22 patients required additional support, some support calls covered multiple topics.

1. Fernandes M, et al. *Int J Clin Pharm*. 2014;36:86-91.

Cladribine tablets 10 mg (3.5 mg/kg cumulative dose over 2 years) are indicated for the treatment of patients with MS in the United States (relapsing forms of MS, including relapsing-remitting disease and active secondary progressive disease, in adults)

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