Year 1 Performance of adveva®, a Patient Support Programme (PSP) for patients taking MAVENCLAD® (cladribine tablets)

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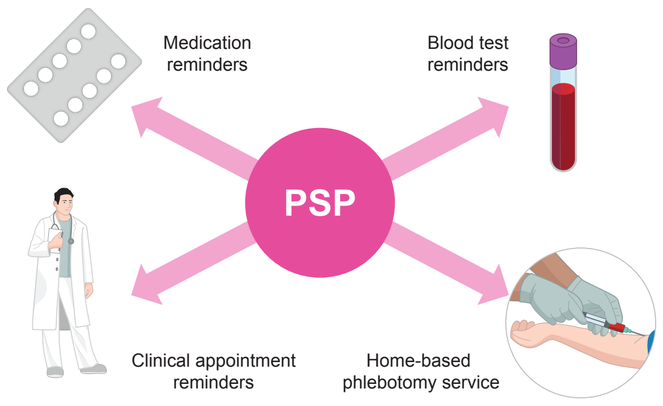
INTRODUCTION

- Cladribine tablets 10 mg, a recent addition to the treatment of relapsing forms of multiple sclerosis (MS), are administered as a cumulative dose of 3.5 mg/kg body weight over 2 years, taken as one treatment course of 1.75 mg/kg/year (each course over weeks 1 and 5 in years 1 and 2).[1]
- Poor adherence to medication corresponds to negative health outcomes, including patient disability progression, morbidity and increased cost of care.[2]
- Individualised treatment support may provide better education and lead to greater treatment adherence by patients, helping to achieve optimal clinical and economic outcomes.[3]
- Merck KGaA provides a free patient support programme (PSP), called adveva®, to support consenting patients prescribed cladribine tablets and who have been enrolled into adveva® by their clinical team 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)**.

Figure 1. Full Support Services of the PSP



PSP, Patient support programme.

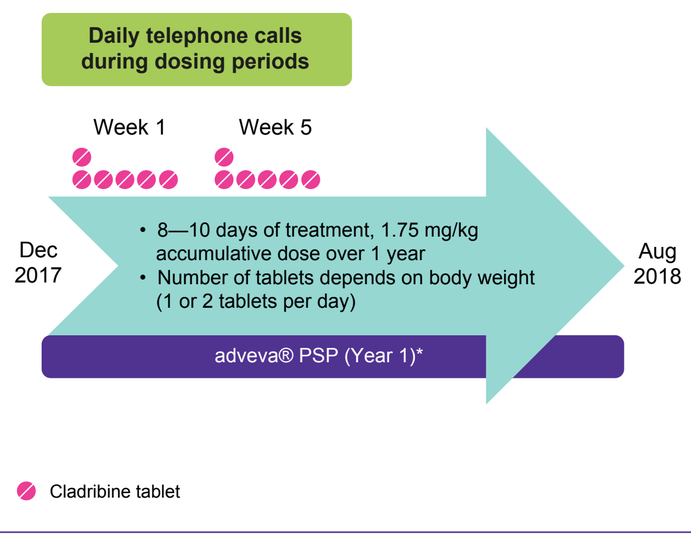
OBJECTIVE

- To evaluate after Year 1, the impact of a proactive telephone-based PSP for UK patients receiving cladribine tablets for highly active relapsing-remitting MS (RRMS).

METHODS

- Aggregated and anonymised telephone conversation records between enrolled patients and the adveva® team were reviewed from December 2017 to August 2018 **(Figure 2)**.
- The analysis considered whether patient-reported adherence was achieved and if basic support (e.g. have you taken your cladribine tablets today?) or additional support was required to achieve the full first year cladribine tablets dose of 1.75 mg/kg.
- Patient reported adherence data are confirmed by the patient and recorded within the independent adveva® data collection system.
- All potential adverse events (AEs) are reported to Merck KGaA, the manufacturer, in accordance with local reporting timelines.
- Transcripts were also assessed to determine the nature of the discussion that patients required when additional support was needed.

Figure 2. PSP Support Between Analysis Time Points



*Includes daily telephone calls during dosing periods, basic support, additional support if required, dose interpretation advice and general patient queries throughout the patient's treatment time. **PSP**, Patient support programme.

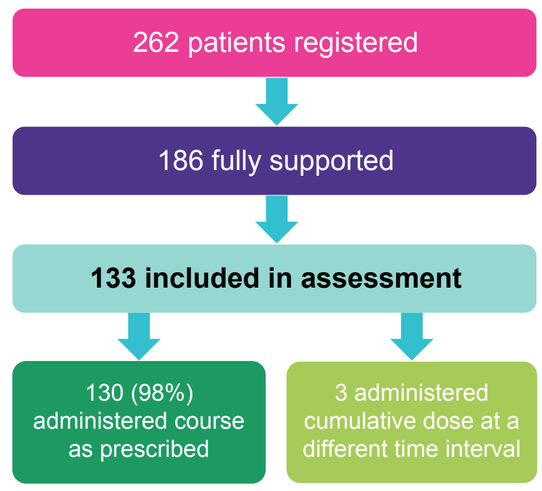
The adveva® Patient Support Programme

- adveva® consists of a nurse-led call centre that proactively calls patients at pre-specified time points along their treatment journey with cladribine tablets.
  - Patients receive daily telephone calls on the days they are taking cladribine tablets and asked to confirm if they have taken their medication as prescribed.
  - If the patient has difficulty interpreting what dose they should take, the adveva® team can advise them, in accordance with their prescription.
  - If patients are concerned about taking cladribine tablets or associated AEs, the adveva® team can use approved scripts to help support the patient or refer them back to their clinical team.
  - adveva® also offers a Q&A service for general patient queries as well as for those patients enrolled on the PSP by their clinical team.

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 (**Figure 3**).
- 133 patients who had passed both week 1 and week 5 time points with cladribine tablets were included in the assessment (**Figure 4**); 53 patients had not yet reached week 5 at the time of assessment.

Figure 3. Patient Flow

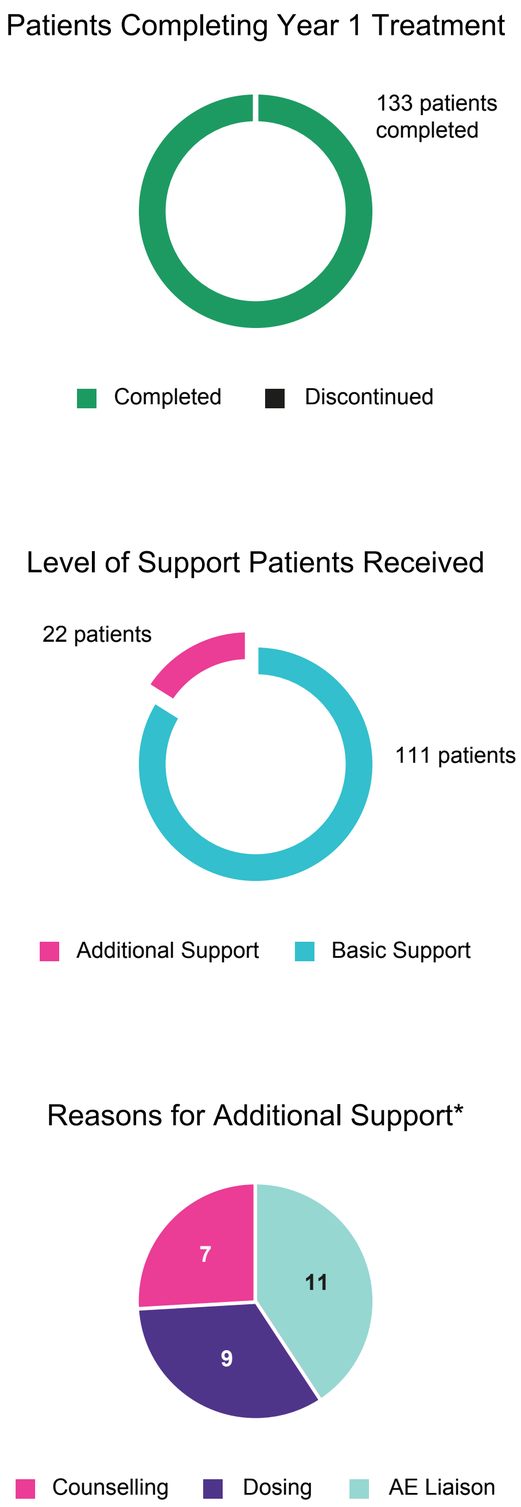


- 100% of patients analysed successfully consumed the cumulative dose of 1.75 mg/kg in the first year.
  - Of the three patients who did not achieve this within the recommended time frame, one patient had a 1-day extension, one took the last dose 1 week late and one administered the second treatment 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**).

CONCLUSIONS

- **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.**
- **The support of a proactive telephone-based PSP was of particular value to the patients who required additional support during their treatment days.**
  - **In the small proportion of patients who required further support, the PSP was able to help them achieve the required dose.**
- **Adherence to disease-modifying drug therapy is a key determinant of treatment effectiveness. Factors affecting effectiveness relate to the drug regimen, patient knowledge about the drug and patient-HCP relationships.[4]**
- **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.**

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



*While 22 patients required additional support, some support calls covered multiple topics. **AE**, adverse event; **PSP**, patient support programme.

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

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DISCLOSURES

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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