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Real-World Evidence With Five-Year Data (2017–2022) on the use of Cladribine Tablets in Patients With Multiple Sclerosis in England: An Updated Analysis From the CLARENCE Study

Wallace Brownlee[1], Amerah Amin[2], Luke Ashton[2], Alex Herbert[2]

[1]Queen Square MS Centre, UCL Institute of Neurology and NIHR UCL Hospitals Biomedical Research Centre, London, UK;
[2]Merck Serono Ltd., Feltham, UK, an affiliate of Merck KGaA

CONCLUSIONS

Five years post-launch, patients treated with cladribine tablets in England show:
- **High rates of treatment persistence and low rates of treatment switching**
- **Stable disability between the first and second courses in the majority of patients who completed the full 2-year treatment**

Cladribine tablets are used early in the treatment pathway:
- **36% of patients were treatment naïve at initiation and 47% received cladribine as a 2nd line treatment**

Findings from this long-term follow-up continue to highlight the real-world effectiveness of cladribine tablets for patients with highly active relapsing MS

INTRODUCTION

- Cladribine tablets have been available in England for the treatment of highly active relapsing multiple sclerosis (MS) since November 2017
- As a compulsory requirement of National Health Service (NHS) reimbursement, all disease-modifying therapies (DMTs) prescribed for MS within NHS England must be registered via the Blueteq® high-cost drug platform[1]
- Data from this platform can provide valuable insights into the patterns of use and effectiveness of cladribine tablets in routine clinical practice, outside of the tightly-controlled randomised controlled trial setting
- Here, we provide an **updated analysis with up to 5 years of data from the CLARENCE study**, a longitudinal, large cohort, observational study using real-world data from the Blueteq® platform

OBJECTIVES

Describe patient characteristics in terms of treatment experience and Expanded Disability Status Scale (EDSS) score

Describe treatment patterns in terms of treatment persistence, which encompasses treatment completion and treatment discontinuation, along with instances of treatment switch

METHODS

- NHS England collect data on use of cladribine tablets via the Blueteq® platform, and provide the associated anonymised patient-level data to the study sponsor on a quarterly basis
- Longitudinal data were collated for patients prescribed cladribine tablets (3.5 mg/kg cumulative dose over 2 years) between November 2017 and November 2022
- To be included in the study, patients must have:
  - ≥1 completed Blueteq® form, and
  - ≥1 invoice record
- At treatment initiation, treatment history (including prior DMT use) and baseline EDSS scores were recorded
- Over the length of the study, the following outcomes concerning **treatment persistence** were evaluated:
  - **Treatment completion**: patients who received both courses (Year 1 and 2) of cladribine (even if a switch was recorded after receiving Year 2 treatment)
  - **Treatment discontinuation**: patients who received one single course of treatment and had ≥18 months of follow-up data without receiving Year 2 of treatment **OR** had switched after receiving Year 1 of treatment (even if follow-up was <18 months)
  - **Treatment switch rate**: patients who switched treatment from cladribine tablets to another DMT at any point after their first dose
- Change in **EDSS score** was also determined (if recorded at the start of the 2nd treatment year for patients with an available Year 2 Blueteq® record)
- Data were analysed descriptively

RESULTS

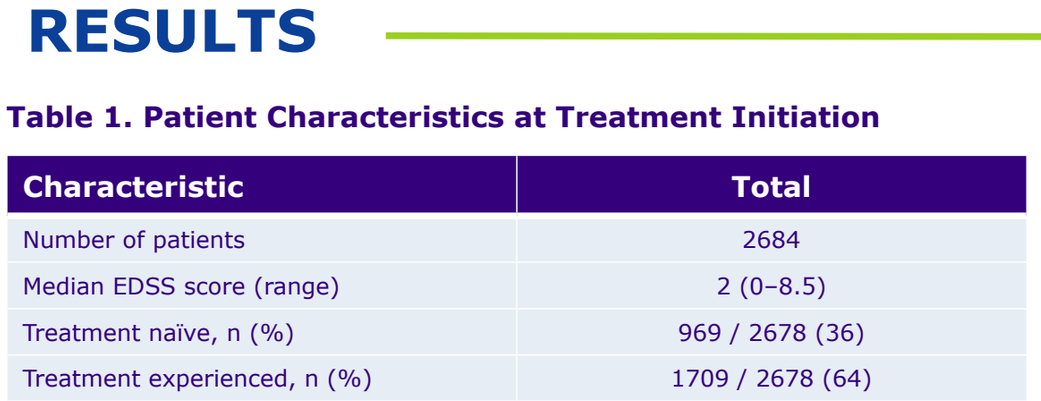
Table 1. Patient Characteristics at Treatment Initiation

Characteristic	Total
Number of patients	2684
Median EDSS score (range)	2 (0–8.5)
Treatment naïve, n (%)	969 / 2678 (36)
Treatment experienced, n (%)	1709 / 2678 (64)
One prior DMT only	1269 (47)
Two prior DMTs	312 (12)
≥ Three prior DMTs	128 (7.5)

DMT, disease-modifying therapy; **EDSS,** Expanded Disability Status Scale

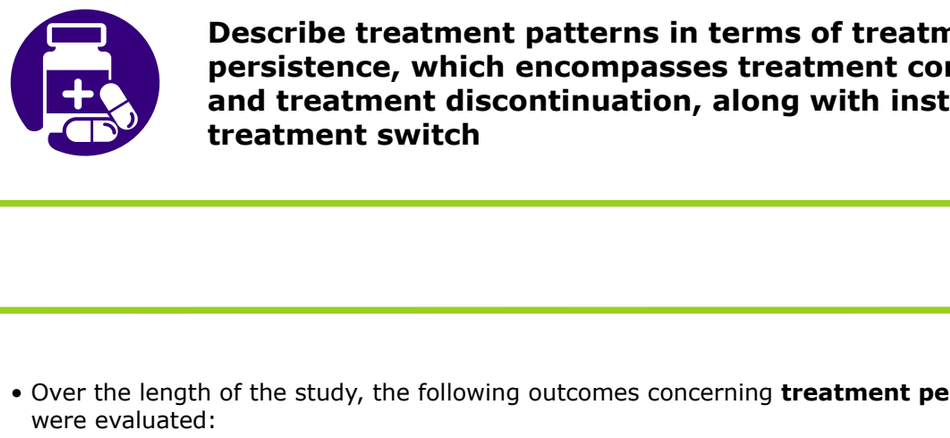
- **2238 (83%)** patients started cladribine as either **treatment naïve** or **1st switch treatment** (i.e., 2nd line)
- **1196 (70%)** treatment-experienced patients received a **platform therapy** before initiating cladribine tablets. Of these:
  - **31% had received a platform injectable**
  - **39% had received a platform oral**

Figure 1. Treatment Persistence (Nov 2017 – Nov 2022; n=2684)



- **11%** of patients **discontinued treatment prior to receiving the full course** of treatment
  - Of these, 96 patients switched to another DMT and 191 patients did not receive a 2nd course of cladribine tablets within 18 months of initiating treatment
  - Treatment discontinuation was more often observed in patients with **higher physical disability (EDSS score ≥4.5)**

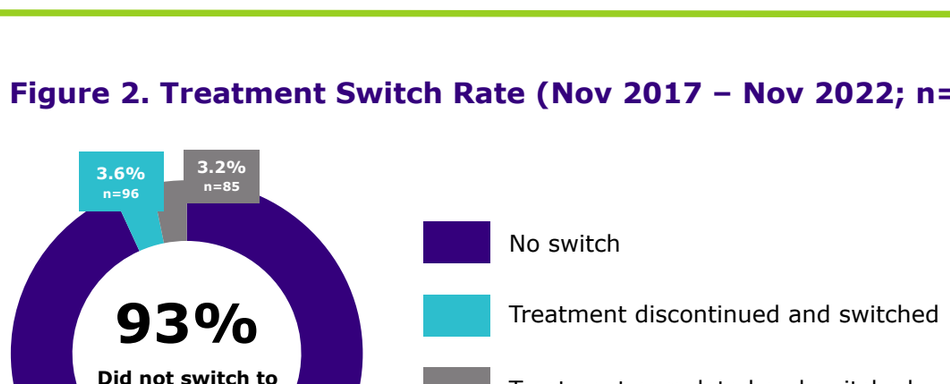
Figure 2. Treatment Switch Rate (Nov 2017 – Nov 2022; n=2684)



DMT, disease-modifying therapy

- Most patients who switched did not receive the full 2-year course of cladribine tablets (n=96, 3.6%)
- 85 patients (3.2%) were known to have switched after completing the 2nd-year course of treatment, primarily in Years 3 and 4
- Switching occurred most frequently in DMT-experienced patients (n=122, 67%)

Figure 3. Change in EDSS Score Between Years 1 and 2 of Treatment With Cladribine Tablets (n=955)*



EDSS, Expanded Disability Status Scale

*Only patients with 2 years of evaluable EDSS scores (955/2684) were included in this analysis.

- For patients with 2 years of evaluable EDSS scores:
  - **85%** had **stable disability** in terms of **no change** or a **decrease (improvement)** in EDSS score
  - **Most patients (73%) did not record a change in EDSS score** between Year 1 and Year 2

REFERENCE:
1. Multiple Sclerosis Trust. Disease modifying drugs (DMDs), updated March 2022 (available at: https://mstrust.org.uk/about-ms/ms-treatments/disease-modifying-drugs-dmds).

DISCLOSURES:
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