RWD 11

Real-World Persistence on Cladribine Tablets of Patients with RMS over 4 years based on Claims Data

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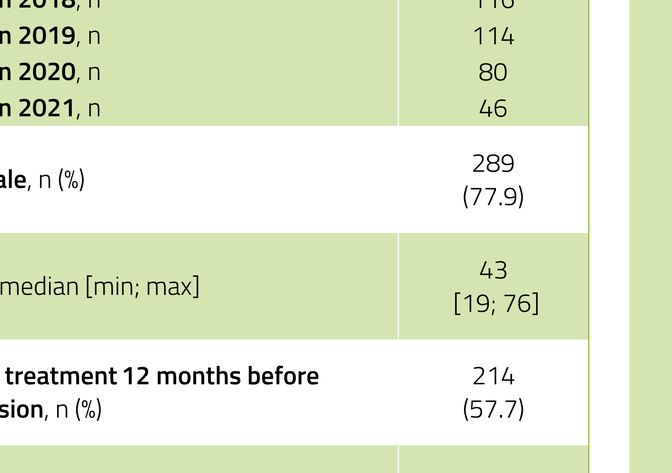
BARMER

Objectives and Background Information

- Cladribine tablets (MAVENCLAD®) have been approved in the EU for the treatment of patients with highly active relapsing multiple sclerosis (RMS) in 2017.[1]



Cladribine tablets follow a pulsed treatment regimen and are administered during two treatment weeks in years 1 and 2, no further treatment is required in year 3 and 4.[2]

- This retrospective analysis aims to assess persistence and switch rates of patients receiving cladribine tablets using real-world claims data.

Methods

- The analyses are based on German statutory health insurance records from BARMER, representing 8.9 million insured persons.
- **Inclusion criteria:**
  - Adult patients with MS diagnosis (ICD-10 G35.x)
  - Initial prescription of cladribine tablets from September 2017 – June 2021
- **Exclusion criteria:**
  - Patients with an exclusive coding PPMS (ICD-10 G35.2), non-active SMPS (ICD-10 G35.30) or non-specific MS (ICD-10 G35.9)
- Prior treatments were recorded for 12 months before cladribine tablets were initiated. The observation period was from September 2017 – December 2021.
- **Analysis sets:**
  - Intitial therapy: RMS patients with initial prescription of cladribine tablets from September 2017 – June 2021
  - Therapy according to SmPC: RMS patients with initial prescription of cladribine tablets from September 2017 – June 2021 with minimum dosage according to SmPC (at least 4 tablets per treatment week)

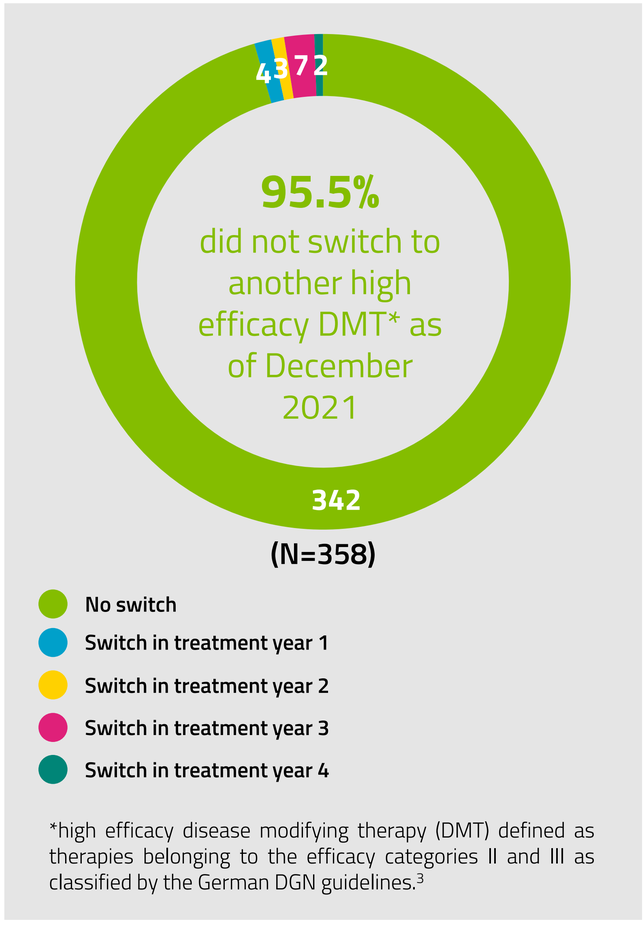
Demographics

Baseline Characteristics

Therapy initiated, n	371
- in 2017, n	15
- in 2018, n	116
- in 2019, n	114
- in 2020, n	80
- in 2021, n	46
Female, n (%)	289 (77.9)
Age, median [min; max]	43 [19; 76]
Prior treatment 12 months before inclusion, n (%)	214 (57.7)
Therapy according to SmPC; n	358

Results

Treatment Persistence



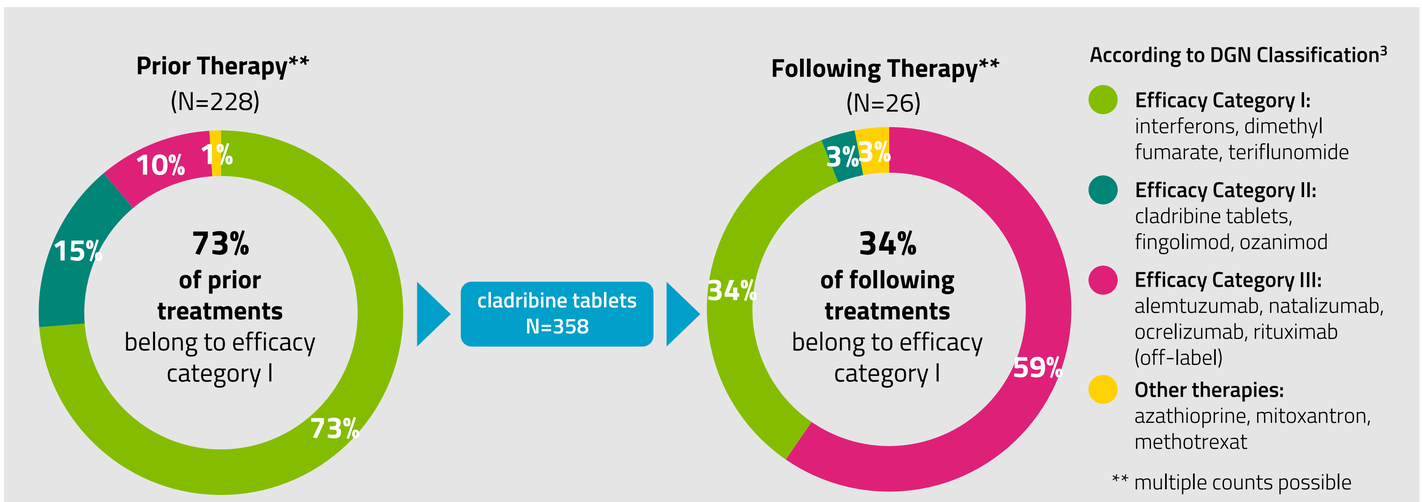
*high efficacy disease modifying therapy (DMT) defined as therapies belonging to the efficacy categories II and III as classified by the German DGN guidelines.[3]

Switch Rate and Time to Switch

Overall switches, n (%)	16 (4.5)
Switch	
- in treatment year 1, n (%)	4 (1.1)
- in treatment year 2, n (%)	3 (0.8)
- in treatment year 3, n (%)	7 (2.0)
- in treatment year 4, n (%)	2 (0.6)
Time in days until prescription of another high efficacy DMT*, median [min; max]	779 [31; 1277]

- 358 patients had started cladribine tablets according to SmPC between September 2017 (Launch) and June 2021.
- In the data analysis set, 16 out of 358 patients switched to another high efficacy DMT, resulting in an overall switch rate of 4.5%.
- Out of these 16 patients 4 switched in their first treatment year, 3/7/2 patients switched in years 2/3/4 respectively.
- Median time to switch from initial prescription of cladribine tablets until prescription of another high efficacy DMT was 779 [31; 1277] days.

Treatment Patterns



- 73% of prior treatments were therapies belonging to efficacy category I, thus the majority of patients who received cladribine tablets escalated their therapy.
- 34% of treatments following cladribine tablets were therapies belonging to the lower efficacy category I, and 59% of the following treatments belong to efficacy category III.

Conclusions

- More than 50% of RMS patients initiated on cladribine tablets were treatment experienced, with therapies belonging to efficacy category I being the most frequently prescribed prior treatments.
- More than 95% of RMS patients initiated on cladribine tablets continued their therapy as directed beyond year 2.
- Under cladribine tablets, there was a low overall switch rate of 4.5%. Only 16 out of 358 patients switched to another high efficacy DMT.
- The median time to switch was more than 2 years.
- In the therapy-free years 3 and 4 only 2% and 0.6% respectively required further high efficacy DMT for RMS.
- Real world data suggest that cladribine tablets are a valid treatment option for RMS with high persistence over the 4 year treatment cycle.

References: *1. EMA Mavenclad Authorisation Details: https://www.ema.europa.eu/en/medicines/human/EPAR/mavenclad (06.09.2023); 2. Mavenclad : EPAR – Product Information: Summary of Product Information, last updated 10/05/2022; 3. Hemmer B. et al., Diagnose und Therapie der Multiplen Sklerose, Neuromyelitis-optica-Spektrum-Erkrankungen und MOG-IgG-assoziierten Erkrankungen, S2k-Leitlinie, 2023, in: Deutsche Gesellschaft für Neurologie (Hrsg.), Leitlinien für Diagnostik und Therapie in der Neurologie. Online: www.dgn.org/leitlinien (06.09.2023).*

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