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CLADRISE Study: Real-World Insights Into Cladribine Tablets Treatment Pathways and Their Impact on Relapse Rates in Multiple Sclerosis

Gregor Fištravec, Jiří Drahota, Dana Horáková, *Gerard Harty*

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RESEARCH IN CONTEXT

1. **60.8% of PwMS who received a full course of cladribine tablets and had at least 4 years' follow-up received no further cladribine tablets treatment or switched to another DMT.**
2. **Over 90% of these PwMS were free of relapse over 4 years.**

OBJECTIVES

Assess the real-world usage patterns of cladribine tablets among people with multiple sclerosis (PwMS) in terms of treatment duration and additional treatment.

INTRODUCTION

CLADRISE is a noninterventional study of cladribine tablets in PwMS using data from the Czech Multiple Sclerosis Registry (ReMuS).

While the early treatment effects and initial safety profile are well described and understood, its **sustained efficacy and extended safety outcomes in the real world** are less explored.

METHODS

- As of December 31, 2023, the ReMuS Registry included records for 21,540 PwMS. We analyzed PwMS aged 18 years or older who initiated treatment with cladribine tablets after European Medicines Agency approval on August 22, 2017.
- PwMS were categorized into one of three groups (Group A received additional cladribine tablets treatment; Group B switched to another DMT; Group C received neither additional cladribine tablets treatment nor switched to a different DMT) based on their treatment course after the initial cladribine tablets treatment (i.e., PwMS who received their full Year 1 and Year 2 treatment as per EU marketing authorization). Groups were further split by Year 5 status to enable future analyses.
- For those who received both additional cladribine tablets treatment and switched to a different disease-modifying therapy (DMT), group assignment was based on the event that occurred first.
- We focused on PwMS with at least 4 years of follow-up to allow consistent comparison across groups.
- The primary endpoint was the proportion who remained relapse-free in Year 4.

METHODS

Group A received additional cladribine tablets treatment
- **Group A1** within the first 4 years
- **Group A2** in Year 5 or later

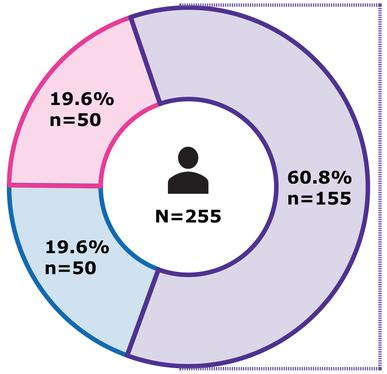
Group B switched to another DMT
- **Group B1** within the first 4 years
- **Group B2** in Year 5 or later

Group C received neither additional cladribine tablets treatment nor switched to a different DMT
- **Group C1** had ≤4 years of follow-up
- **Group C2** had ≤5 years of follow-up

RESULTS

- Out of 1040 PwMS initiating cladribine tablets, 255 PwMS had at least 4 years of follow-up (**Figure 1**).

Figure 1. Treatment Pathways for PwMS With at Least 4 Years Follow-Up

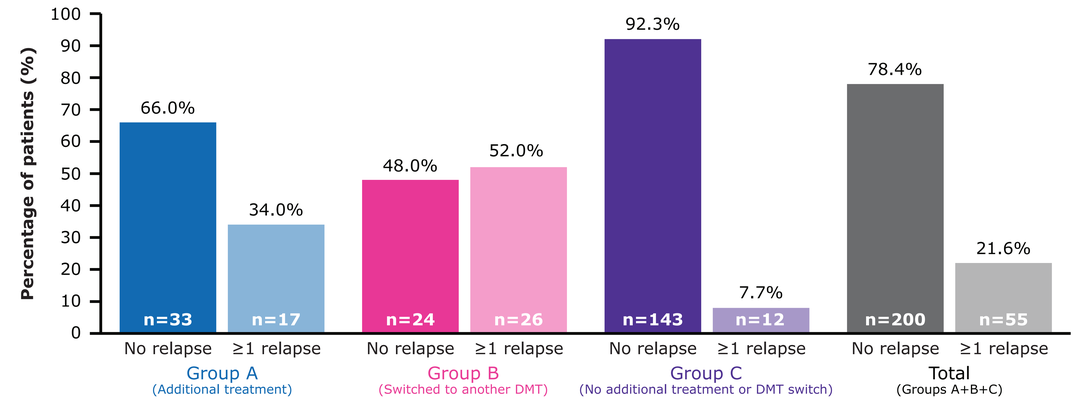


60.8% of PwMS not requiring additional treatment or a switch after at least 4 years since cladribine tablets initiation

DMT, disease-modifying therapy; PwMS, people with multiple sclerosis

- By Year 4, the total proportion of PwMS who experienced no relapses versus those with one or more relapses was 78% without relapses versus 22% with at least one relapse. By group: Group A: 66% without relapses versus 34% with at least one relapse; Group B: 48% without relapses versus 52% with at least one relapse; Group C: 92% without relapses versus 8% with at least one relapse (**Figure 2**).
- In Group A, 58% of patients experienced relapses in the year preceding additional treatment and 16% in the year after additional treatment.

Figure 2. Proportion of PwMS Who Experienced no Relapses Versus Those With One or More Relapses in Year 4



DMT, disease-modifying therapy; PwMS, people with multiple sclerosis

CONCLUSIONS

- **More than 60% of PwMS did not require additional treatment with cladribine tablets and did not switch to other DMTs during at least 4 years of follow-up.**
  - **Of these, over 90% remained relapse-free over the 4-year period.**
- **Further analysis will be conducted as the cohorts mature.**

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Supplementary Materials

Author affiliations
Gregor Fištravec[1,2], Jiří Drahota[1,2], Dana Horáková[2], Gerard Harty[3]

[1]ReMuS, The Czech Republic Multiple Sclerosis Patient Registry, Prague, Czech Republic; [2]Department of Neurology and Center of Clinical Neuroscience, First Faculty of Medicine Charles University and General University Hospital in Prague, Prague, Czech Republic; [3]the healthcare business of Merck KGaA, Darmstadt, Germany

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