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Clinical Outcomes in Patients with COVID-19 Infection During Phase IV Studies of Cladribine Tablets for Treatment of Multiple Sclerosis

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Disclosures

This study was sponsored by Merck KGaA, Darmstadt, Germany.

- **RK** is a consultant to Merck KGaA, Darmstadt, Germany.
- **SR** is an employee of Merck, Aubonne, Switzerland, a division of Merck KGaA, Darmstadt, Germany.
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INTRODUCTION

- COVID-19 has become a significant concern for patients with MS and their healthcare providers,[1] prompting various recommendations on the appropriate use of DMDs such as cladribine tablets.
- As of 29 June 2020, there were 46 patients treated with cladribine tablets and with confirmed or suspected COVID-19 (Merck KGaA safety database).[2]
  - The majority of patients had mild to moderate respiratory symptoms.[2]
  - Includes several patients from ongoing Phase IV studies.

1. Giovannoni G, et al. *Mult Scler Relat Disord.* 2020;39:102073. 2. Giovannoni G, et al. Poster presentation at ACTRIMS-ECTRIMS 2020 (LB1151).
DMD, disease-modifying drug; **MS**, multiple sclerosis

OBJECTIVES

To report on clinical outcomes in patients with MS who developed COVID-19 infection during two ongoing Phase IV studies of cladribine tablets (CLARIFY-MS and MAGNIFY-MS).

MS, multiple sclerosis

METHODS

- Both studies utilize an **open-label**, **single-arm**, **multicenter** design.
  - **CLARIFY-MS** is investigating the effect of cladribine tablets on health-related quality of life in patients with highly active relapsing MS.
  - **MAGNIFY-MS** aims to determine the onset of action of cladribine tablets in patients with highly active relapsing MS.

Patients treated with cladribine tablets 10 mg (3.5 mg/kg cumulative dose over 2 years).

680 patients are continuing in both studies.

Three cases of suspected COVID-19 infection were identified from adverse event reports in the studies

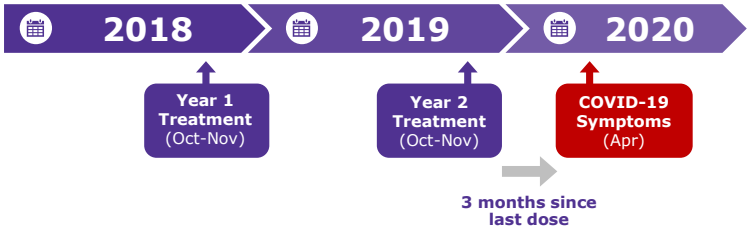
MS, multiple sclerosis

Patient #1 (CLARIFY-MS)

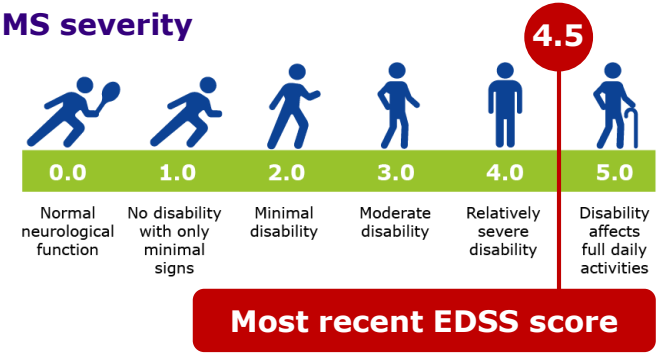
Patient background

- aged 57 years
- 21-year history of MS
- Concomitant cardiovascular disease / asthma and prior DMD use (interferons)
- Baseline lymphocyte count 1.48 G/L

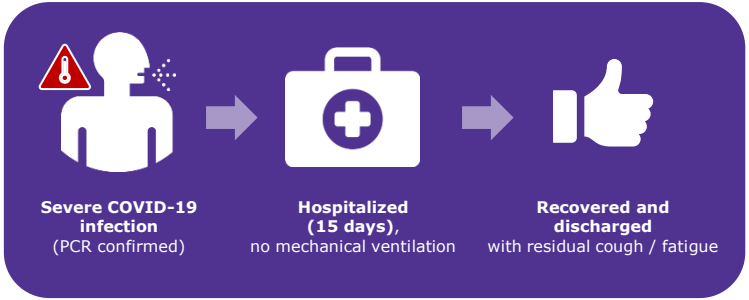
Time between last dose and COVID-19 onset



MS severity



COVID-19 course



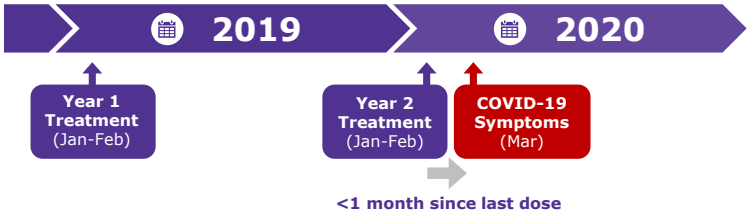
DMD, disease-modifying drug; **EDSS**, Expanded Disability Status Scale; **MS**, multiple sclerosis

Patient #2 (CLARIFY-MS)

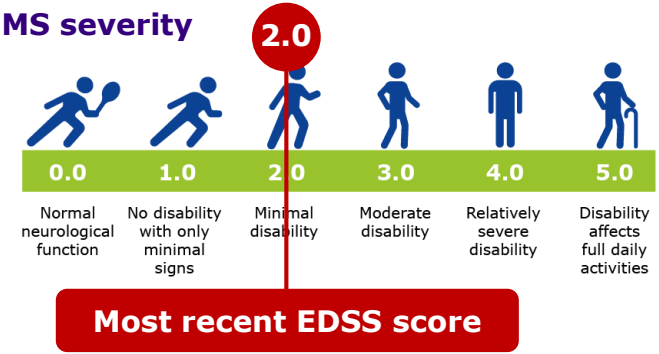
Patient background

aged 32 years
2-year history of MS
Previous deep vein thrombosis during pregnancy and no prior DMDs
Baseline lymphocyte count 2.80 G/L

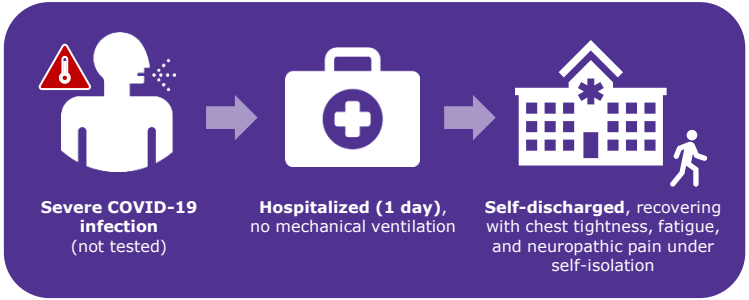
Time between last dose and COVID-19 onset



MS severity



COVID-19 course



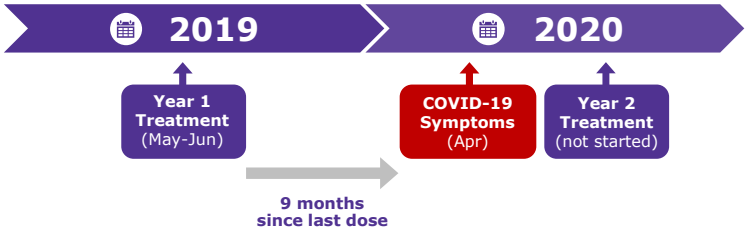
DMD, disease-modifying drug; **EDSS**, Expanded Disability Status Scale; **MS**, multiple sclerosis

Patient #3 (MAGNIFY-MS)

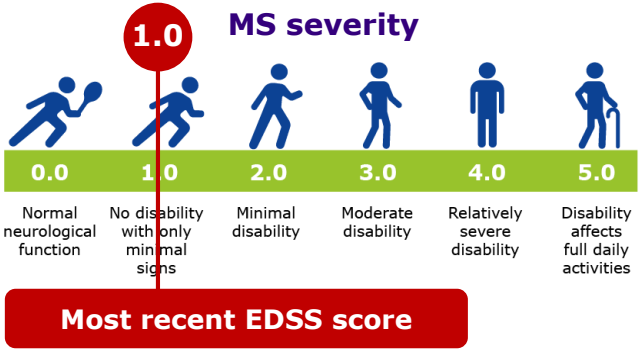
Patient background

♂ aged 31 years
7-year history of MS
Prior use of interferon β-1a
Baseline lymphocyte count 2.39 G/L

Time between last dose and COVID-19 onset



MS severity



COVID-19 course

DMD, disease-modifying drug; **EDSS**, Expanded Disability Status Scale; **MS**, multiple sclerosis

CONCLUSIONS

We describe the clinical course of 3 patients who developed COVID-19 infection during two ongoing Phase IV studies of cladribine tablets.

All 3 patients have recovered or are recovering and none required mechanical ventilation.