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:
RK is a consultant to the healthcare business of Merck KGaA, Darmstadt, Germany.

SR is an employee of Ares Trading SA, Eysins, Switzerland, an affiliate of Merck KGaA, Darmstadt, Germany.

NA is an employee of the healthcare business of Merck KGaA, Darmstadt, Germany.

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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

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 DMTs such as cladribine tablets
- As of 29 June 2020, there were 46 patients treated with cladribine tablets 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

OBJECTIVE

- **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)**

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

RESULTS

Patient #1 (CLARIFY-MS)

Patient background

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

Time between last dose and COVID-19 onset

MS severity

COVID-19 course

Patient #2 (CLARIFY-MS)

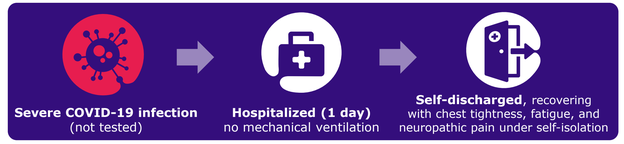
Patient background

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

Time between last dose and COVID-19 onset

MS severity

COVID-19 course

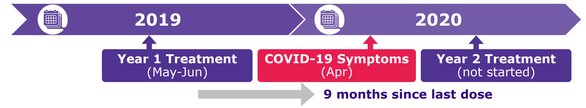


Patient #3 (MAGNIFY-MS)

Patient background

- Male 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

Abbreviations: **DMT**, disease-modifying therapy; **EDSS**, Expanded Disability Status Scale; **MS**, multiple sclerosis; **PCR**, polymerase chain reaction | **References**: 1. Giovannoni G, et al. *Mult Scler Relat Disord*. 2020;39:102073. 2. Giovannoni G, et al. Poster presentation at ACTRIMS-ECTRIMS 2020 (LB1151).

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SCAN FOR FULL AUTHOR DISCLOSURE DETAILS