

Clinical Outcomes in Patients With COVID-19 During Two Phase IV Studies of Cladribine Tablets for Treatment of Multiple Sclerosis: An Update

V. Yavorskaya, R. Karan, L. Borsi, N. Alexandri

ACKNOWLEDGMENTS

Medical writing assistance was provided by Steve Winter of inScience Communications, Springer Healthcare Ltd, UK, and was funded by the healthcare business of Merck KGaA, Darmstadt, Germany.

DISCLOSURES

VY, **RK**, and **LB** are consultants to the healthcare business of Merck KGaA, Darmstadt, Germany. **NA** is an employee of the healthcare business of Merck KGaA, Darmstadt, Germany.

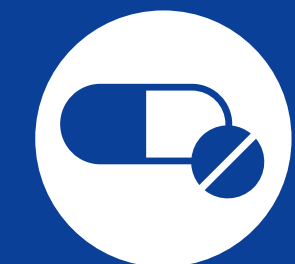
Clinical Outcomes in Patients With COVID-19 During Two Phase IV Studies of Cladribine Tablets for Treatment of Multiple Sclerosis: An Update

V. Yavorskaya¹, R. Karan¹, L. Borsi¹, N. Alexandri¹

¹the healthcare business of Merck KGaA, Darmstadt, Germany



CONCLUSIONS



Findings show that the small number of patients who acquired COVID-19 in these Phase IV studies of cladribine tablets typically experienced mild disease with no increased risk of serious outcomes.

In this limited cohort, there was no relationship between last dose of treatment with cladribine tablets and onset of COVID-19.



INTRODUCTION

- The COVID-19 pandemic prompted various guidelines and expert opinions on the appropriate use of disease-modifying therapy for multiple sclerosis (MS),^[1,2] including cladribine tablets.
- As of November 24, 2021, there were 632 patients treated with cladribine tablets and with confirmed or suspected COVID-19.^[3]
 - Findings show that such patients were generally not at greater risk of serious disease and/or a severe outcome compared with the general population who acquired COVID-19.^[3]



OBJECTIVE

To report on clinical outcomes in patients with MS who developed COVID-19 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, and were ongoing at time of reporting (July 31, 2021).
 - 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.
- Cases of suspected or confirmed COVID-19 in these studies were identified from adverse event (AE) reports and reviewed in terms of patient characteristics, COVID-19 severity, and outcomes.



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



755 patients are continuing in both studies. CLARIFY-MS, n=485 MAGNIFY-MS, n=270



RESULTS

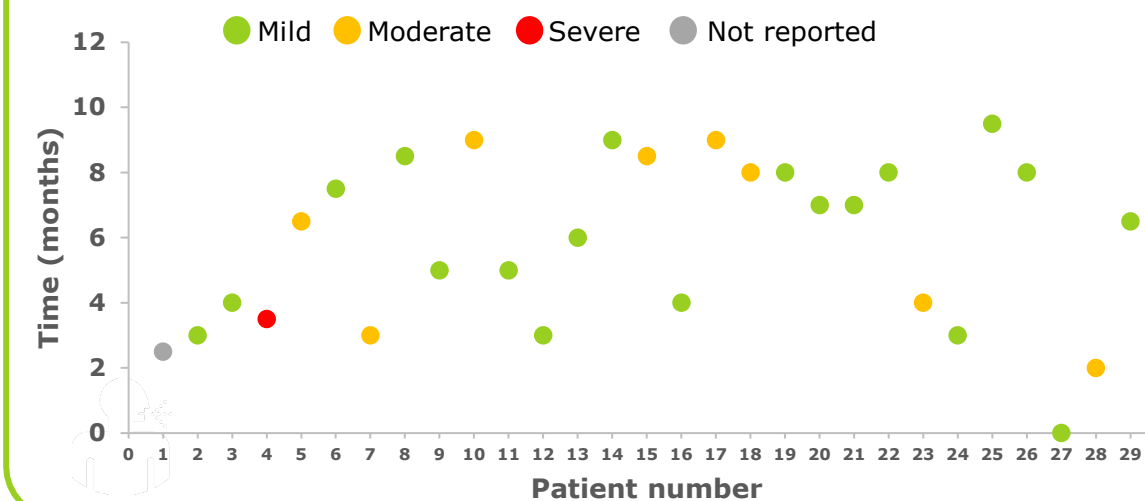
Patient Characteristics

- From the combined population (n=755), 30 patients were identified with either suspected (n=2) or confirmed (n=28) COVID-19.
- The majority of affected patients were female (25 out of 30 patients), consistent with the proportion of females in the CLARIFY-MS and MAGNIFY-MS studies (~70%).
- Patients were aged 19–55 years.

Time to Onset of COVID-19

- Time to onset of COVID-19 since last dose of cladribine tablets was 0–11 months (**Figure 1**).
- There was no clustering of COVID-19 cases at any point since last treatment dose, including the time of expected lymphocyte nadir.

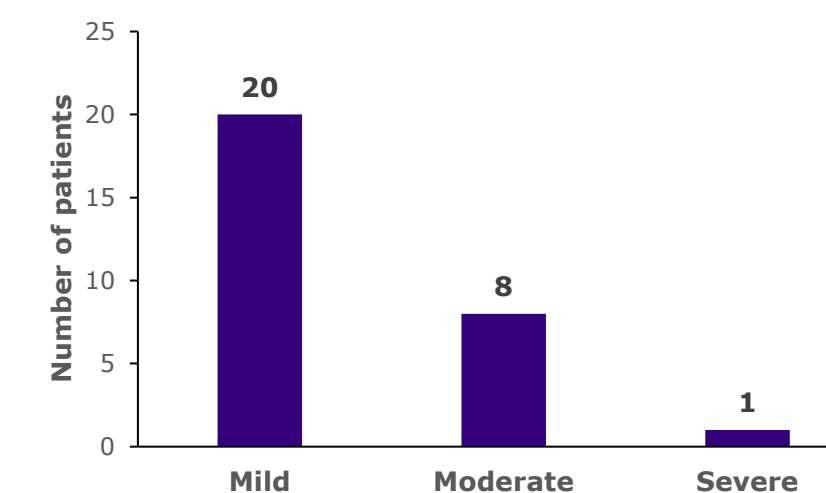
Figure 1. Time to Onset of COVID-19 Since Last Dose of Cladribine Tablets, by Patient



Severity of COVID-19 and Outcomes

- The majority of patients experienced mild infection (**Figure 2**).
- At time of reporting, 27 out of 30 patients had recovered and 3 patients recovered with sequelae.

Figure 2. Severity of COVID-19 (n=29)*



*Severity of COVID-19 was not reported for one patient

Serious COVID-19 Cases

- Three cases of COVID-19 were reported as serious AEs, including two patients who were hospitalized.
- No patient required mechanical ventilation and there were no deaths.

REFERENCES

1. Giovannoni G, et al. *Mult Scler Relat Disord*. 2020;39:102073. 2. Reyes S, et al. *J Neuroimmunol*. 2021;357:577627. 3. Giovannoni G, et al. Poster presentation at ACTRIMS 2022 (P106).

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The CLARIFY-MS study: NCT03369665; the MAGNIFY-MS study: NCT03364036.

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INTRODUCTION

- The COVID-19 pandemic prompted various guidelines and expert opinions on the appropriate use of DMTs for MS,^[1,2] including cladribine tablets.
- As of November 24, 2021, there were 632 patients treated with cladribine tablets and with confirmed or suspected COVID-19.^[3]
 - Findings show that such patients were generally not at greater risk of serious disease and/or a severe outcome compared with the general population who acquired COVID-19.^[3]



OBJECTIVE

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

DMT, disease-modifying therapy; MS, multiple sclerosis

REFERENCES

1. Giovannoni G, et al. *Mult Scler Relat Disord*. 2020;39:102073. 2. Reyes S, et al. *J Neuroimmunol*. 2021;357:577627. 3. Giovannoni G, et al. Poster presentation at ACTRIMS 2022 (P106).



METHODS

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MS, multiple sclerosis



RESULTS

Patient Characteristics

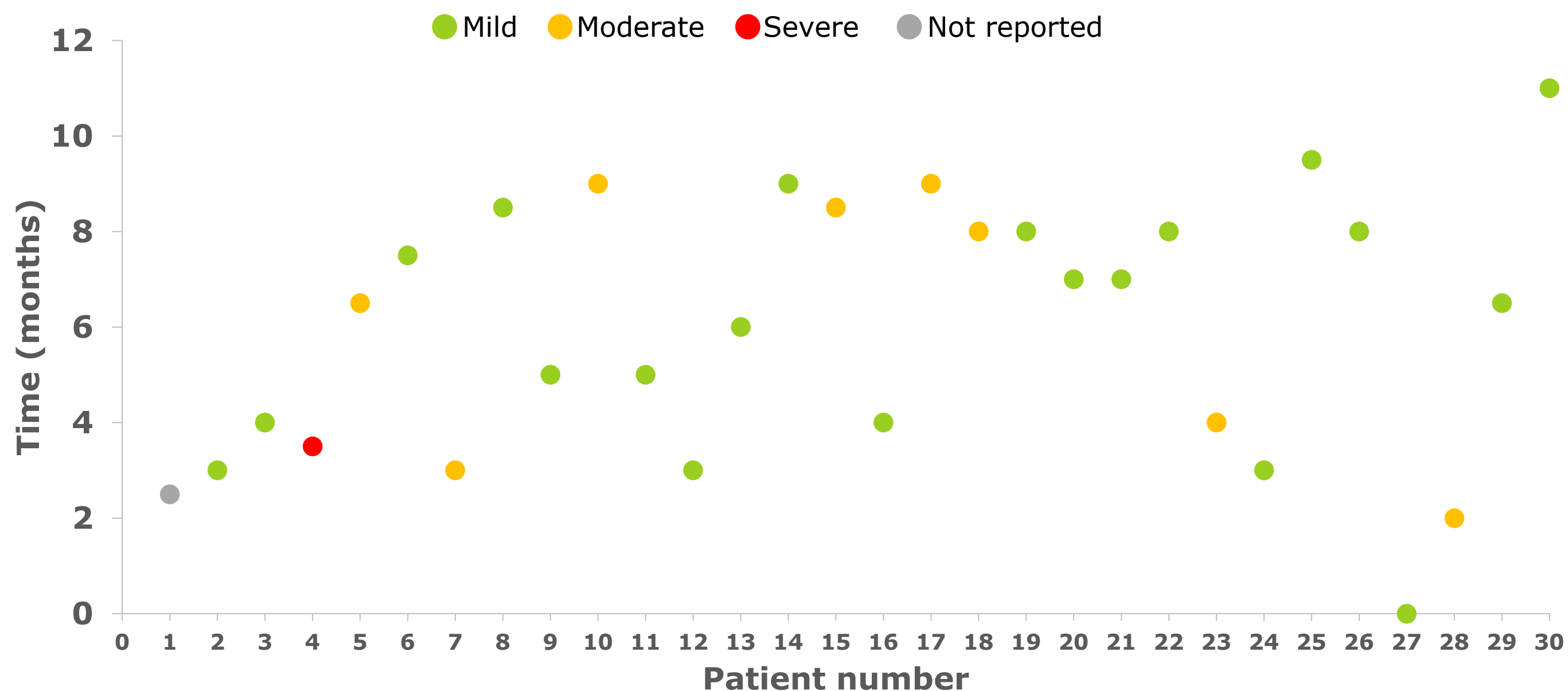
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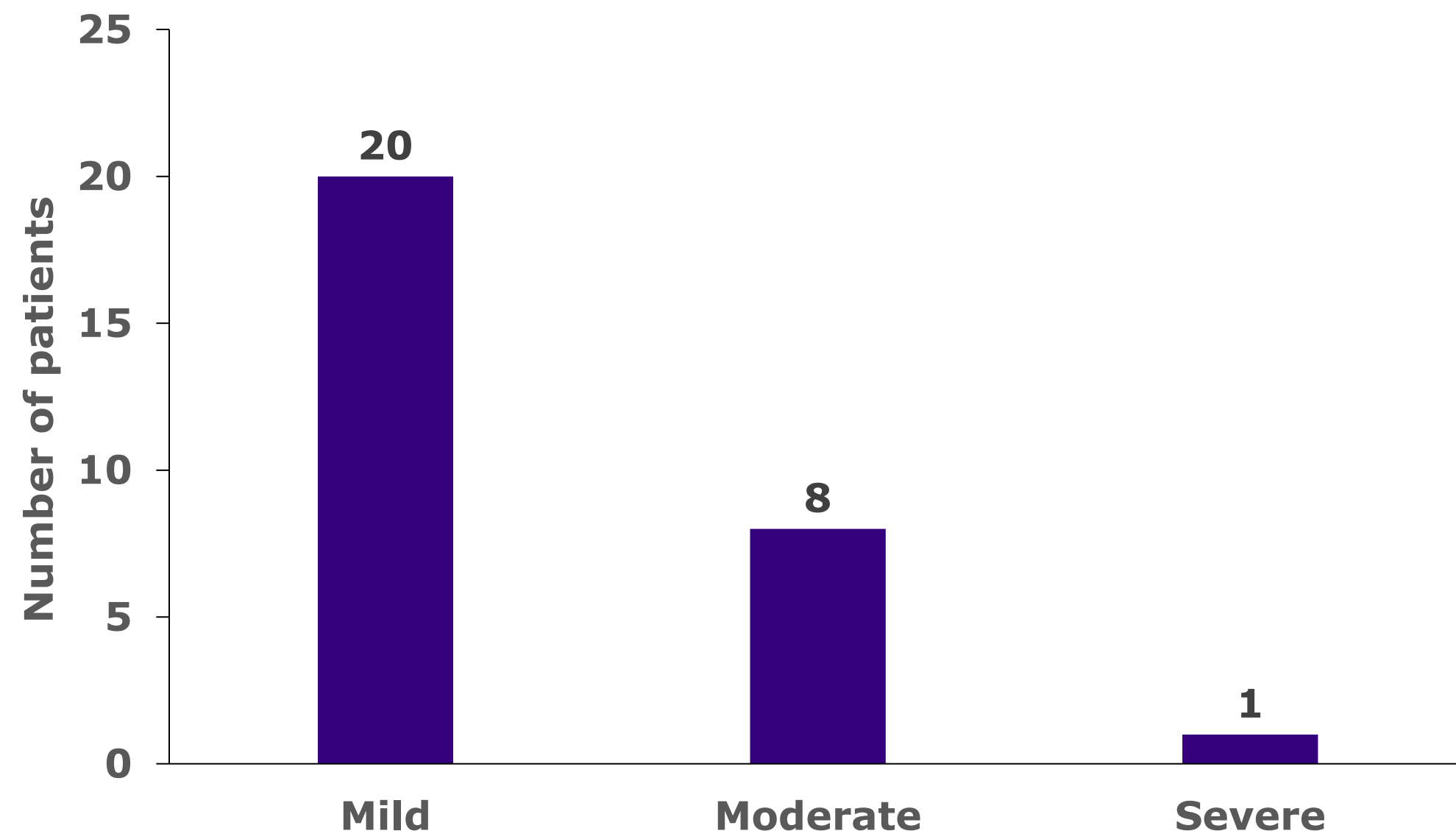




RESULTS

Severity of COVID-19 and Outcomes

- The majority of patients (20 out of 29 patients)* experienced mild infection.
- At time of reporting, 27 out of 30 patients had recovered and 3 patients recovered with sequelae.



Serious COVID-19 Cases

- Three cases of COVID-19 were reported as serious adverse events, including two patients who were hospitalized.
- No patient required mechanical ventilation and there were no deaths.

*Severity of COVID-19 was not reported for one patient



CONCLUSIONS

- **Findings show that the small number of patients who acquired COVID-19 in these Phase IV studies of cladribine tablets typically experienced mild disease with no increased risk of serious outcomes.**
- **In this limited cohort, there was no relationship between last dose of treatment with cladribine tablets and onset of COVID-19.**