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COVID-19 outcomes in fingolimod- or siponimod - treated patients: clinical trial and post marketing cases

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Introduction: Understanding how immunomodulatory therapies influence COVID-19 outcomes in people living with multiple sclerosis (PlwMS) is vital to patients and physicians alike.
Aims and Objective: Evaluate COVID-19 outcomes in PlwMS receiving either fingolimod or siponimod.
Methods: The Novartis clinical trial (CT) and safety databases were reviewed to identify confirmed (CT: confirmed if patient is SARS COV-2 positive; post-marketing [PM]: considered as reported) or suspected cases of COVID-19 in PlwMS receiving either fingolimod or siponimod (CT cut-off: fingolimod 04-Aug-2021, siponimod 29-Oct-2021; PM cut-off: fingolimod 28-Feb-2022, siponimod 25-Mar-2022).
Results: For fingolimod, there were 1054 cases comprising of 45 suspected (PM=45) and 1009 confirmed cases (CT=9; PM=1,000) of COVID-19 (mean age in years: 17 [CT], 43 [PM]; female: 71% [715/1009; CT=4, PM=711]; male: 25% [254/1009; CT=5, PM=249] and not reported: 4% [40/1009; PM=40]). Of these, 35% (358/1009; CT=8, PM=349) were from Europe, 30% (305/1009; PM=305) from the US and 34% (347/1009; CT=1, PM=346) from the rest of the world (ROW). Hospitalisation was required for 13% of patients (130/1009; PM=130); 1% (13/1009; PM=13) had a fatal outcome; and 43% (437/1009; CT=9, PM=428) recovered or were recovering at the most recent follow-up.
For siponimod there were 321 cases comprising of 6 suspected (CT=1; PM=5) and 315 confirmed cases (CT=53; PM=262) of COVID-19 (mean age in years: 49 [CT], 53 [PM]; female: 68% [214/315; CT=34, PM=180]; male: 28% [88/315; CT=19, PM=69] and not reported: 4% [13/315; PM=13]). Of these, 53% (168/315; CT=6, PM=162) were from the US; 30% (96/315; CT=46, PM=50) from Europe; and 16% (51/315; CT=1, PM=50) from the ROW. Hospitalisation was required for 19% of patients (60/315; CT=15, PM=45); 2% (7/315; CT=3, PM=4) had a fatal outcome; and where information was provided 42% (131/315 CT=50, PM=81) recovered or were recovering at the most recent follow-up.
Conclusions: Available data indicates that most COVID-19 cases among PlwMS treated with fingolimod or siponimod were non-serious. Among PlwMS exposed to disease-modifying therapies (DMTs), the reported hospitalisation and mortality rates are 12.8%–21.5% and 1.62%–3.5%, respectively (Reder et al 2021; Sormani et al 2022). Thus, hospitalisation and fatality rates with siponimod and fingolimod in these series of Novartis reported cases were similar to those observed in PlwMS on other DMTs.
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RS is an employee of Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA.
AK and VDH are employees of Novartis Pharma AG, Basel, Switzerland.
BH has served on scientific advisory boards for Novartis. He has served as Data Monitoring and Safety Committee member for AllergyCare, Polpharma, and TG therapeutics. He or his institution have received speaker honoraria from Desitin. His institution received research grants from Regeneron for MS research. He has been funded by the EU project Multiple MS, the excellence cluster Synergy, and the BMBF funded project Clinspect. He holds part of 2 patents. One for the detection of antibodies against KIR4.1 in a subpopulation of patients with MS and the other for genetic determinants of neutralizing antibodies to interferon
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BJW serves on a scientific advisory board for Novartis and reports personal fees from Novartis for this activity. He is also a medical officer for Medicago Inc and holds parts of patents for vaccines targeting influenza, Clostridioides difficile, and Schistosomamansoni. In the last 5 years, he has held academic industry awards with Medicago, MIT Canada, and Aviex Technologies.