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Siponimod stabilises physical disability scores in people living with secondary progressive multiple sclerosis after 2 years of treatment: analysis from the novartis global managed access program

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Introduction: In the Phase III EXPAND trial, siponimod demonstrated significant reductions in the risk of confirmed disability progression (CDP) and confirmed worsening of cognitive processing speed in comparison to placebo (broad secondary progressive MS [SPMS] population). However, most regions (including European Union) approved siponimod for the treatment of active SPMS. Real-world effectiveness data for siponimod in the clinical setting are still scarce.
Objectives: To describe demographic and clinical characteristics and characterise EDSS score changes in people living with SPMS (plwSMPS) receiving siponimod under the manage access program (MAP): Global Siponimod MAP cohort (BAF2001M cohort).
Methods: The BAF2001M cohort is an umbrella program Novartis implemented to facilitate patient access to siponimod when marketing authorisation is pending (under physician request) in the absence of satisfactory alternative therapies. The program started in March 2019 and is on-going. Target population included adult patients with SPMS diagnosis and EDSS score <7 from Mar 2019-Jan 2021. From Jan 2021 onward access to the MAP required SPMS with active disease. Treatment selection and patient monitoring was based on physician assessment. No regular visits or data entry or collection were mandatory. Baseline characteristics include country, age, gender, relapse, MRI activity in the last 2 years, EDSS, and cognition evaluation.
Results: A total of 632 cases were analysed (153 excluded from the analysis due to local country restrictions). Mean age was 52.3 (SD: 8.7) years, 60% were females, and median EDSS was 5.5 (interquartile range: 4.5-6.5). Around 51% had a relapse in the last 2 years, 54% had prior cognitive evaluation, and 52% had an MRI scan in the last 2 years (48% showed activity). Mean change in EDSS from baseline was around -0.02/-0.03 at the Months 6, 12, 18, and 24 (not statistically significantly different from baseline). Approximately 94% (140/149) patients improved or were stable at Month 24. Further analysis to be presented at congress.
Conclusion: In a heterogenous cohort of 620 plwSPMS (including non-active SPMS) receiving siponimod in a real-world clinical setting, the vast majority improved or stabilised their EDSS score over 2 years. Interestingly, this patient population was older than the EXPAND study population and, with approximately half demonstrating relapse/MRI activity, supports siponimod's effectiveness in a broad SPMS population.
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Virginia de las Heras, **Suzannah Ryan**, **Roxana Oana Istrate**, **Soudeh Ansari**, **Sophie Arnould**, and **Daniela Piani-Meier** are employees of Novartis.