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Long-Term Efficacy and Safety of Siponimod in Active SPMS and Overall SPMS Populations: Expand Study Data up to 5 Years

Bruce A.C. Cree, MD, PhD, MAS[1], Gavin Giovannoni, MD, PhD[2], Ralf Gold, MD[3], Robert J. Fox, MD[4], Patrick Vermersch, MD, PhD[5], Ralph H.B. Benedict, PhD[6], Amit Bar-Or, MD[7], Nicolas Rouyrre, MSc[8], Daniela Piani-Meier, PhD[8], Shannon Ritter, MS[9], Ajay Kilaru, MBBS[8], Frank Dahlke, MD[8], Goeril Karlsson, PhD[8] and Ludwig Kappos, MD[10], (1)Department of Neurology, UCSF Weill Institute for Neurosciences, University of California San Francisco, San Francisco, CA, (2)Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, United Kingdom, (3)Department of Neurology, St Josef-Hospital, Ruhr-University Bochum, Bochum, Germany, (4)Mellen Center for Treatment and Research in Multiple Sclerosis, Neurological Institute, Cleveland, OH, (5)Department of Neurology, University of Lille, CHU Lille, LIRIC-U995, FHU-Imminent, Lille, France, (6)Department of Neurology, University at Buffalo, Buffalo, NY, (7)Center for Neuroinflammation and Experimental Therapeutics and Department of Neurology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, (8)Novartis Pharma AG, Basel, Switzerland, (9)Novartis Pharmaceuticals Corporation, East Hanover, NJ, (10)Research Center for Clinical Neuroimmunology and Neuroscience Basel (RC2NB), Departments of Medicine, Clinical Research, Biomedicine and Biomedical Engineering, University Hospital and University of Basel, Basel, Switzerland

Abstract Text:

Background: In the EXPAND Core study, siponimod significantly reduced the risk of 3-/6-months(m) confirmed disability progression (3m/6mCDP) and 6m confirmed ≥4-points clinically meaningful worsening on Symbol Digit Modalities Test (6mCW_{SDMT}) vs placebo in the active SPMS subgroup (aSPMS, presence of relapses 2 years before screening and/or ≥1 T1 gadolinium-enhancing lesion at baseline) and overall SPMS population.

Objectives: Assess long-term efficacy and safety of siponimod in aSPMS and overall SPMS population from the Core and Extension parts of EXPAND.

Methods: This analysis included Core and 36m extension data from all study participants who received ≥1 dose of siponimod 2 mg or placebo (cut-off 06Apr2019; total study duration of ≤5 years). Time-to-6mCDP by Expanded Disability Status Scale, time-to-6mCW_{SDMT} and annualized relapse rate (ARR) were assessed for the Continuous (siponimod in Core+Extension) and Switch (placebo in Core and open-label siponimod in Extension) groups. Safety was also evaluated.

Results: Of 1651 SPMS patients randomized in the EXPAND Core part, 1224 (74%) patients entered Extension (878 [72%] ongoing). Of 779 patients with aSPMS randomized in the Core part, 582 entered Extension. In the Continuous vs Switch group, 6mCDP risk was reduced by 29% (p=0.0044) and 22.3% (p=0.0026) in aSPMS and the overall population; time to reach the 25th 6mCDP percentile was delayed by 78% and 54%, respectively. Time for 50% of patients to reach 6mCDP in aSPMS and the overall population was 48m and 51.7m respectively for Switch group. For the Continuous group, less than 50% reached 6mCDP. In the Continuous vs Switch group, 6mCW_{SDMT} risk was reduced by 33% (p=0.0018) and 23% (p=0.0047) in aSPMS and the overall population; time to reach the 25th 6mCW percentile was delayed by 45% and 62%, respectively. Median time-to-6mCW_{SDMT} (55.5m) was reached only for the Switch group in the aSPMS cohort. ARR reduction was significant in the Continuous vs Switch group across aSPMS (39.7%; p=0.0023) and overall (52%; p<0.0001) populations. Incidence rates of adverse events/100 patient-years in both populations were consistent over the long-term period with no new safety findings observed.

Conclusions: The differences in sustained treatment effects (disability, relapse and cognitive processing speed) over the long-term period between Continuous siponimod and placebo-Switch groups highlight the benefit of early siponimod treatment initiation in SPMS. The safety profile remained favorable and consistent with previous reports.

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Submitter's E-mail Address:
saimithra.thammera@novartis.com

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First Presenting Author

Presenting Author

Bruce Cree, MD, PhD, MAS
Email: Bruce.Cree@ucsf.edu -- Will not be published

Department of Neurology, UCSF Weill Institute for Neurosciences, University of California San Francisco
San Francisco CA
USA

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Second Author

Gavin Giovannoni, MD, PhD
Email: g.giovannoni@qmul.ac.uk -- Will not be published

Blizard Institute, Barts and The London School of Medicine and Dentistry, Queen Mary University of London
London
United Kingdom

Click to view Conflict of Interest Disclosure

Third Author

Ralf Gold, MD
Email: ralf.gold@rub.de -- Will not be published

Department of Neurology, St Josef-Hospital, Ruhr-University Bochum
Bochum
Germany

Click to view Conflict of Interest Disclosure

Fourth Author

Robert Fox, MD
Email: FOXR@ccf.org -- Will not be published

Mellen Center for Treatment and Research in Multiple Sclerosis, Neurological Institute
Cleveland OH
USA

Click to view Conflict of Interest Disclosure

Fifth Author

Patrick Vermersch, MD, PhD
Email: patrick.vermersch@univ-lille.fr -- Will not be published

Department of Neurology, University of Lille, CHU Lille, LIRIC-U995, FHU-Imminent
Lille
France

Click to view Conflict of Interest Disclosure

Sixth Author

Ralph Benedict, PhD
Email: benedict@buffalo.edu -- Will not be published

Department of Neurology, University at Buffalo
Buffalo NY
USA

Click to view Conflict of Interest Disclosure

Seventh Author

Amit Bar-Or, MD
Email: amitbar@pennmedicine.upenn.edu -- Will not be published

Center for Neuroinflammation and Experimental Therapeutics and Department of
Neurology, Perelman School of Medicine, University of Pennsylvania
Philadelphia PA
USA

Click to view Conflict of Interest Disclosure

Eighth Author

Nicolas Rouyrre, MSc
Email: nicolas.rouyrre@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Ninth Author

Daniela Piani-Meier, PhD
Email: daniela.piani_meier@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Tenth Author

Shannon Ritter, MS
Email: shannon.ritter@novartis.com -- Will not be published

Novartis Pharmaceuticals Corporation
East Hanover NJ
USA

Click to view Conflict of Interest Disclosure

Eleventh Author

Ajay Kilaru, MBBS
Email: ajay.kilaru@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Twelfth Author

Frank Dahlke, MD
Email: frank.dahlke@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Thirteenth Author

Goeril Karlsson, PhD
Email: goeril.karlsson@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Click to view Conflict of Interest Disclosure

Fourteenth Author

Ludwig Kappos, MD
Email: Ludwig.Kappos@usb.ch -- Will not be published

Research Center for Clinical Neuroimmunology and Neuroscience Basel (RC2NB),
Departments of Medicine, Clinical Research, Biomedicine and Biomedical Engineering,
University Hospital and University of Basel
Basel
Switzerland

Click to view Conflict of Interest Disclosure

First Contact

Suzannah Ryan, PhD
Email: suzannah.ryan_ext@novartis.com -- Will not be published

Novartis Pharma AG
Basel
Switzerland

Second Contact

Saimithra Thammera, MPharm
Email: saimithra.thammera@novartis.com -- Will not be published

Novartis Healthcare Private Limited
Hyderabad
India

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