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EVALUATING NO EVIDENCE OF DISEASE ACTIVITY (NEDA) WITH OZANIMOD IN PATIENTS WITH RELAPSING MULTIPLE SCLEROSIS (RMS): POST HOC ANALYSIS OF PHASE 3 RADIANCE AND DAYBREAK

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Objective To assess NEDA-3 and NEDA-4 in RMS patients treated with ozanimod.

Methods Data are from a randomized phase 3 trial (RADIANCE-NCT02047734) of oral ozanimod 0.92 mg/d vs intramuscular interferon β -1a (IFN) 30 μ g/wk and an open-label extension trial (DAYBREAK-NCT02576717) of ozanimod 0.92 mg/d. NEDA-3 (no gadolinium-enhancing lesions, new/enlarging T2 lesions, relapses, and Expanded Disability Status Scale score progression) and NEDA-4 (NEDA-3 plus annualized whole brain volume loss \leq 0.4%) were calculated from RADIANCE baseline and rebaselined to RADIANCE month 12 to control for high lesion activity and brain volume loss rates immediately after treatment initiation (observed cases).

Results NEDA-3 rates at RADIANCE month 12 and 24 and DAYBREAK month 12, 24, and 36 were 31.2%, 24.6%*, 16.2%*, 13.4%*, and 10.7% with continuous ozanimod and 26.9%, 17.0%, 9.8%, 8.6%, and 7.4% for those on/transitioned from IFN (IFN \rightarrow ozanimod), respectively. NEDA-4 rates were 21.5%, 14.0%*, 10.0%, 10.4%, and 10.3% for continuous ozanimod and 16.3%, 7.8%, 5.9%, 6.2%, and 6.3% for IFN \rightarrow ozanimod. After rebaselining to month 12, NEDA-3 rates at RADIANCE month 24 and DAYBREAK month 12, 24, and 36 were 52.6%*, 33.1%*, 26.3%*, and 21.3% with continuous ozanimod and 33.4%, 20.5%, 17.4%, and 14.8% for IFN \rightarrow ozanimod. Rebaselined rates of NEDA-4 were 33.5%*, 20.0%*, 16.7%, and 14.1% for continuous ozanimod and 19.7%, 11.7%, 11.2%, and 11.0% for IFN \rightarrow ozanimod.

Conclusions More patients achieved NEDA-3 and NEDA-4 at month 24 with ozanimod vs IFN. Rebaselining to month 12 resulted in more patients on continuous ozanimod vs IFN \rightarrow ozanimod achieving NEDA-3 and NEDA-4 in DAYBREAK.

* $P < 0.05$ vs IFN.

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TREATMENT EXPECTATIONS OF ADULTS LIVING WITH SPINAL MUSCULAR ATROPHY

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Objective Evidence is emerging that new therapies may provide effective treatment for adults with spinal muscular atrophy (SMA). We aimed to understand expectations of treatment within the adult SMA community in Australia.

Methods Expressions of interest to participate in focus groups were sought from the adult SMA community through social media and recommendations from treating neurologists. Purposive sampling was used to ensure broad geographic and phenotypic representation. Focus groups were conducted over zoom with neurologist facilitation. Each session involved three, 30 minutes blocks covering expectations, assessments and treatments. Sessions were recorded and transcribed verbatim. Qualitative analysis was performed using reflexive thematic analysis.

Results Nine sessions of 1 to 6 participants were conducted in December 2021. Twenty-eight adults with SMA (non-sitters 13, sitters 8, stand/walkers 7) participated with representation from all states (except ACT). Participants defined treatment effectiveness as stabilisation or slowed decline of existing functional abilities, with any improvement considered a bonus. There was concern that existing methods for evaluating treatment outcomes may not be sensitive enough to detect clinically meaningful changes such as endurance and small movements. Extensive discussion occurred regarding factors that contribute to quality of life. Participants emphasised the importance of maintaining abilities that corresponded with independence such as driving a powerchair, adjusting bed covers and blowing one's own nose. These expectations were realistic when compared with outcomes from observational studies.

Conclusions Adults living with SMA are hopeful that treatment will confer stabilisation or slowing of disease progression leading to prolonged maintenance of existing level of independence.

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SIGNIFICANTLY INCREASING INCIDENCE AND PREVALENCE OF MULTIPLE SCLEROSIS IN GREATER HOBART, TASMANIA, AUSTRALIA

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