

Ozanimod Long-Term Safety and Efficacy

Results from the recently completed DAYBREAK extension trial

The publication of this infographic was supported by Bristol Myers Squibb.

Citation: *Neurol AMJ*. 2024;1[1]:64-65. <https://doi.org/10.33590/neurolamj/IYAW3561>.

Ozanimod

S1P receptor 1 and 5 modulator for relapsing forms of MS in adults, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease^{1,2}

Administration leads to dose-dependent redistribution of lymphocytes to lymph nodes³

DAYBREAK OLE Final Analysis

- At DAYBREAK start: N=736 switched from IFNβ-1a/week, N=877 switched from OZA 0.46 mg/day
- N=881 took OZA 0.92 mg/day continuously from parent trial start through OLE

74.8 Months' mean exposure **15,556.2** Patient year's exposure

Safety

Rates of TEAEs for all participants in DAYBREAK^{4,5} The safety findings were consistent with phase 3 trials^{5,6}

N=2,494 Phase I-III trial completers enrolled in DAYBREAK OLE trial and received OZA 0.92 mg/day

Discontinued due to a TEAE **3.9%**

Any TEAE **89.0%** Serious TEAE **15.3%** Severe TEAE **9.6%**

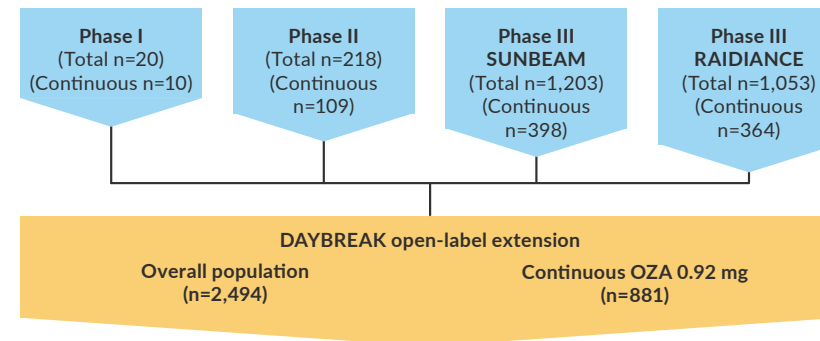
Most common TEAEs (>5%)

Nasopharyngitis (21.3%),	Back Pain (9.6%),	Arthralgia (6.5%),
Headache (17.1%),	ALC decreased (9.4%),	Bronchitis (6.3%),
COVID-19 (16.5%),	Hypertension (9.2%),	Treatment-related depression (5.9%),
URTI (12.4%),	GGT increased (8.0%),	Viral RTI (5.8%),
Lymphopenia (10.3%),	UTI (6.8%),	ALT increased (5.1%),
	RTI (6.6%),	

17 deaths at DAYBREAK end due to:

- COVID-19 and related pneumonia (n=4), malignancies (n=4), accidents (n=2), pulmonary embolisms (n=2), right lung abscess, heart failure, intracerebral hemorrhage, pneumonia, sudden death (n=1 each)

OLE Study Design

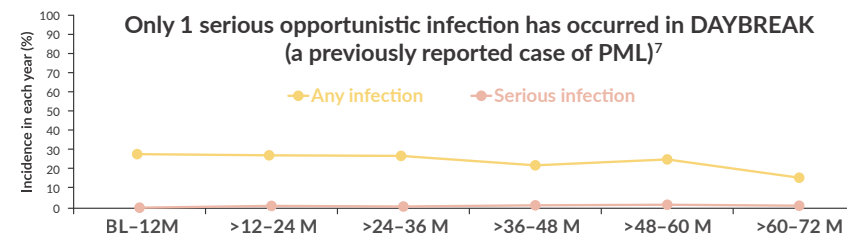


Baseline Demographics

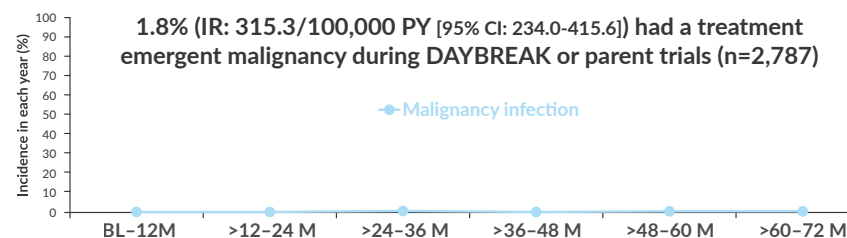
- 66.9% female, 99.2% White, 90.1% Eastern European
- Mean age at symptom onset: 29.5 (SD: 8.9) years; mean age at DAYBREAK baseline: 37.7 (SD 9.2) years

In a post hoc analysis conducted in the patients who went from Phase III trials to DAYBREAK (n=2,256), safety over time was evaluated by year.

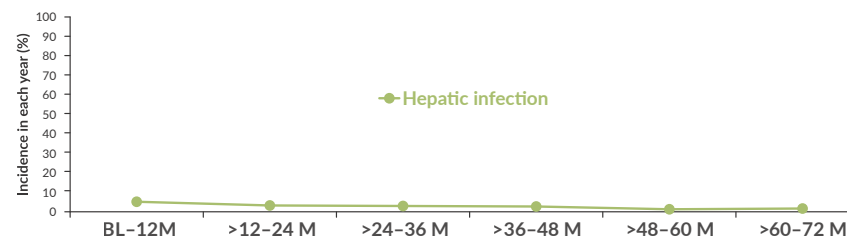
Infection TEAEs



Malignancy TEAEs



Hepatic TEAEs

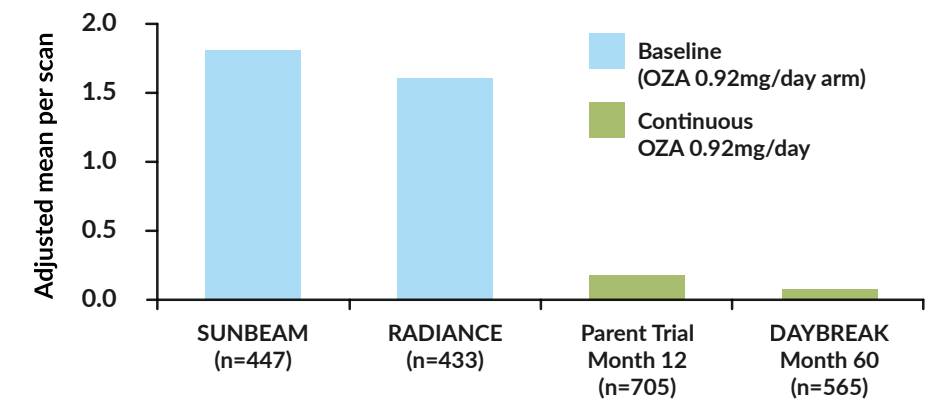


Efficacy

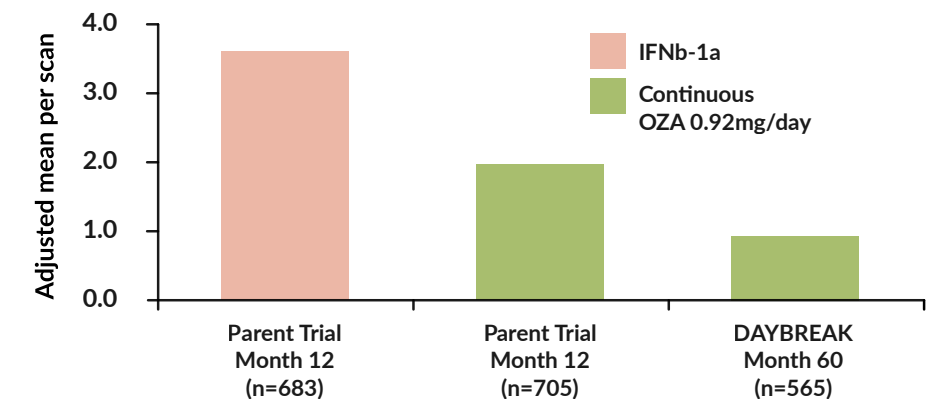
Sustained treatment efficacy in DAYBREAK participants continuously taking OZA 0.92 mg/day from parent trial start⁴

0.09 Adjusted ARR (n=879) **77.9%** Showed no 3-CDP up to 7 years (N=760) **22.1%** Experienced 3-CDP (N=760)

Gadolinium Enhancing Lesions



New/Enlarging T2 Lesions



Key: ALC: absolute lymphocyte count; ALT: alanine transaminase; ARR: annualized relapse rate; GdE: gadolinium-enhancing; GGT: gamma-glutamyltransferase; IR: interquartile range; OLE: open label extension; OZA: ozanimod; IFN: interferon; mo: month; MS: multiple sclerosis; PML: progressive multifocal leukoencephalopathy; RTI: respiratory tract infection; S1P: sphingosine 1-phosphate; SE: standard error; SD: standard deviation; TEAE: treatment emergent adverse event; URTI: upper respiratory tract infection; UTI: urinary tract infection.

References:

- European Medicines Agency (EMA). ZEPOSIA® (ozanimod) Summary of product characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/zeposia-epar-product-information_en.pdf. Last accessed: 16 May 2024.
- Bristol Myers Squibb (BMS). ZEPOSIA® US Prescribing Information. 2023. Available at: https://packageinserts.bms.com/pi/pi_zeposia.pdf. Last accessed: 16 May 2024.
- Harris S et al. Effect of the sphingosine-1-phosphate receptor modulator ozanimod on leukocyte subtypes in relapsing MS. *Neurol Neuroimmunol Neuroinflamm*. 2020;7(5):e839.
- Selmaj KW et al. Long-term safety and efficacy of ozanimod in relapsing multiple sclerosis: final analysis of the DAYBREAK open-label extension study. P090. ACTRIMS Forum 2024, February 29-March 2, 2024.
- Selmaj KW et al. Safety patterns over time with ozanimod during an open-label extension trial in patients with relapsing multiple sclerosis. Presentation P012. AAN Annual Meeting, April 13-18, 2024.
- Cohen JA et al. Safety and efficacy of the selective sphingosine 1-phosphate receptor modulator ozanimod in relapsing multiple sclerosis (RADIANCE): a randomised, placebo-controlled, phase 2 trial. *Lancet Neurol*. 2016;15:373-81.
- Cree BA et al. Long-term safety and efficacy of ozanimod in relapsing multiple sclerosis: up to 5 years of follow-up in the DAYBREAK open-label extension trial. *Mult Scler*. 2022;28(12):1944-62.