Ozanimod Long-Term Safety and Efficacy

Results from the recently completed DAYBREAK extension trial

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This infographic was first published online 30th May 2024.
Since then an erratum was made, which can be found here.

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 nodes[3]

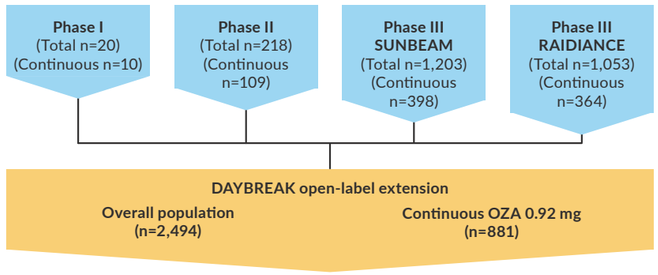
DAYBREAK OLE Final Analysis

- At DAYBREAK start: N=736 switched from IFNb-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

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

Efficacy

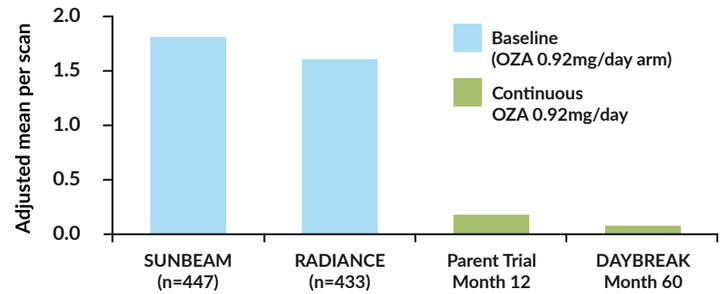
Sustained treatment efficacy in DAYBREAK participants continuously taking OZA 0.92 mg/day from parent trial start[4]

0.09
Adjusted ARR
(n=879)

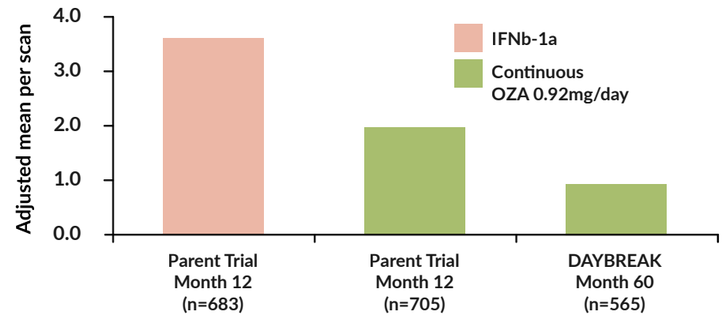
77.9%
Showed no 3-CDP up to 7 years
(N=760)

22.1%
Experienced 3-CDP
(N=760)

Gadolinium Enhancing Lesions



New/Enlarging T2 Lesions



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	Serious TEAE	Severe TEAE
89.0%	15.3%	9.6%

Most common TEAEs (>5%)

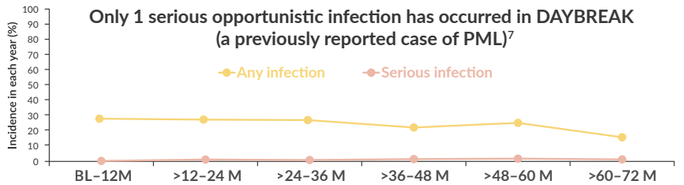
Nasopharyngitis (21.3%), Headache (17.1%), COVID-19 (16.5%), URTI (12.4%), Lymphopenia (10.3%), Back Pain (9.6%), ALC decreased (9.4%), Hypertension (9.2%), GGT increased (8.0%), UTI (6.8%), RTI (6.6%), Arthralgia (6.5%), Bronchitis (6.3%), Treatment-related depression (5.9%), Viral RTI (5.8%), ALT increased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

17 deaths at DAYBREAK end due to:

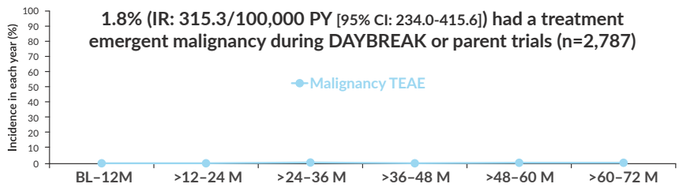
- COVID-19 and related pneumonia (n=4), malignancies (n=4), accidents (n=2), pulmonary embolisms (n=2), right lung abscess, heart failure, intracerebral hemorrhage, pneumonia, sudden death (n=1 each)

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.

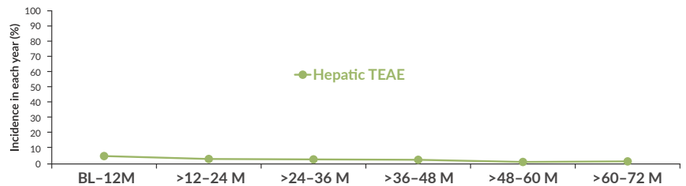
Infection TEAEs



Malignancy TEAEs



Hepatic TEAEs



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-phospate; SE: standard error; SD: standard deviation; TEAE: treatment emergent adverse event; URTI: upper respiratory tract infection; UTI: urinary tract infection.

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3. 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
4. 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.
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