

Evaluation of Disability Outcomes from the Open-Label Extension of CALLIPER: A Phase 2 Trial of Vidofludimus Calcium In Progressive Multiple Sclerosis



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Conclusions

- In the phase 2 CALLIPER trial in progressive multiple sclerosis (PMS) and the exploratory open label extension (OLE), treatment with vidofludimus calcium (VidoCa) showed favorable disability trends, including improvement, that were sustained up to 4.3 years of follow-up. Overall tolerability in the OLE remained favorable with low discontinuation rates.

Background & Aims

- Vidofludimus calcium is under investigation for the treatment of relapsing and progressive forms of MS.
- Vidofludimus calcium's proposed dual mechanism combines direct activation of nuclear receptor-related 1 (Nurr1), a transcription factor implicated in neuronal survival, with selective inhibition of dihydroorotate dehydrogenase (DHODH).
- The PMS Phase 2 CALLIPER study, a randomized, double-blind, placebo (PBO)-controlled study, did not meet its primary endpoint of annualized percent brain volume change; however, positive trends were seen in secondary and exploratory disability measures¹.
- Of the 467 patients that entered the CALLIPER study at baseline (BL), 387 (82.8%) participants entered the OLE.

Methods

- During the MT which extended from 72-120 weeks, participants had the option to switch to 45 mg of vidofludimus calcium from PBO (or continue vidofludimus calcium if in the treatment arm) on or after week 72 and continue into the OLE for up to 8 years of follow-up.
- This study reports confirmed disability worsening (CDW), confirmed disability improvement (CDI), and adverse events in the OLE through the cut-off date (Jan 27, 2026).
- Disability change was defined as a change in BL extended disability status scale (EDSS) score of at least 1.0 point if the BL EDSS was ≤ 5.5 or a change of ≥ 0.5 point if BL EDSS was > 5.5 .
- Outcomes presented here should be interpreted with caution as the OLE data is limited by potential bias, lack of blinding, missing data, and small sample sizes.

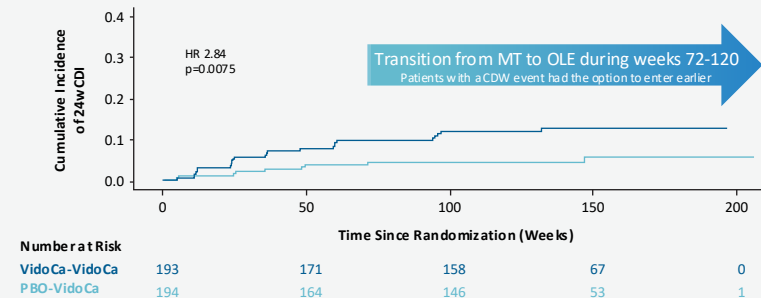
Results

Table 1. Baseline characteristics in participants entering OLE

	VidoCa-VidoCa (n=193)	PBO-VidoCa (n=194)	Total (n=387)
Disease Subtype at Screening			
• PPMS	66 (34.2%)	65 (33.5%)	131 (33.9%)
• naSPMS	108 (56.0%)	112 (57.7%)	220 (56.8%)
• aSPMS	19 (9.8%)	17 (8.8%)	36 (9.3%)
Median (Q1-Q3) EDSS at BL	5.5 (4.0-6.0)	5.5 (4.5-6.0)	5.5 (4.0-6.0)
Median (Q1-Q3) EDSS at OLE BL	5.5 (4.0-6.0)	6.0 (4.5-6.5)	6.0 (4.5-6.5)
No Evidence of Gd+ Lesions at BL	163 (84.5%)	165 (85.1%)	328 (84.8%)
Sex			
• Female	128 (66.3%)	118 (60.8%)	246 (63.6%)
• Male	65 (33.7%)	76 (39.2%)	141 (36.4%)
Mean (SD) Age in Years	50.3 (9.3)	49.1 (10.2)	49.7 (9.7)
Mean (SD) # of Relapses 24 Months Prior to BL and During MT	0.1 (0.2)	0.1 (0.3)	0.1 (0.3)

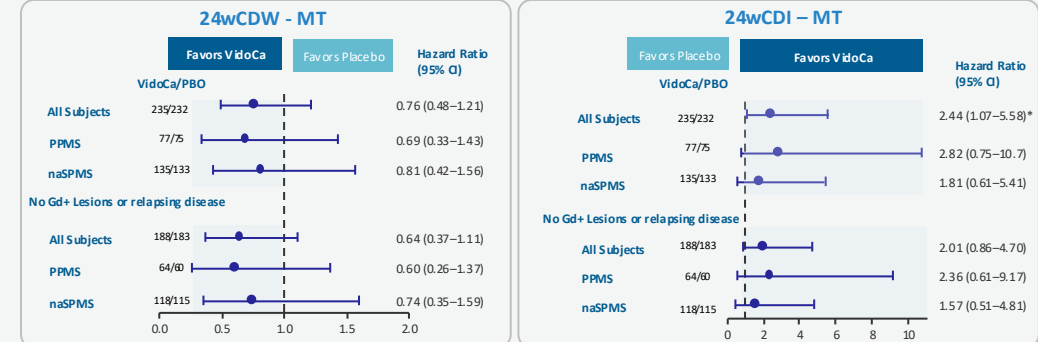
- 93.8% of patients had ≥ 48 weeks of OLE exposure and 23.3% ≥ 72 weeks in the OLE.
- Discontinuation rate was low through the OLE (6.5% through cutoff).

Figure 2: Time to 24wCDI during MT through OLE cut off



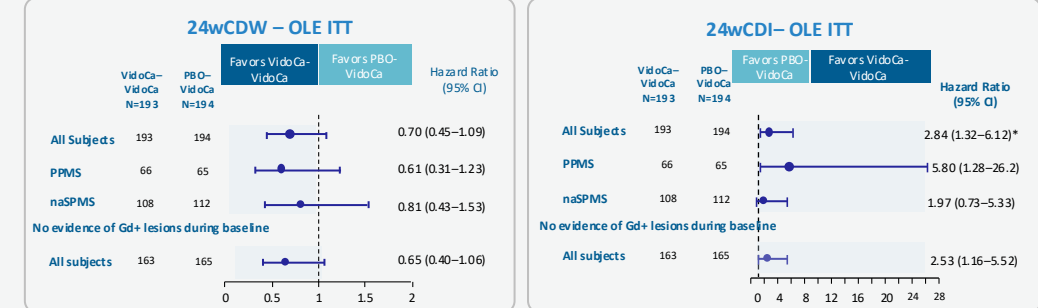
- CDI trends seen in the MT were sustained in the OLE, with participants treated with vidofludimus calcium-vidofludimus calcium showing higher incidence of 24wCDI than participants randomized to the PBO arm at BL.

Figure 1: Exploratory 24-week CDW and CDI outcomes by subgroup at MT end



- Participants treated with vidofludimus calcium had favorable trends in CDW and a nominally significant effect in CDI (all subjects, *p=0.034). These trends were seen across subgroups.

Figure 3: Exploratory 24-week CDW and CDI outcomes by subgroup through OLE cut off



- Favorable disability trends on CDW and CDI seen in the MT were sustained in the OLE, with a nominally significant effect in CDI seen in participants in the vidofludimus calcium-vidofludimus calcium arm compared to the PBO-VidoCa arm (all subjects, *p=0.0075).

Treatment Emergent Adverse Events (TEAEs) in the OLE

Among the 387 participants who entered the OLE, total exposure to vidofludimus calcium in OLE was approximately 494 person-years. 172 participants (44.4%) experienced at least one TEAE, including 22 participants (5.7%) who experienced a serious TEAE. Liver-related TEAEs occurred in 12 participants (3.1%). TEAEs leading to discontinuation occurred in 7 participants (1.8%). Death was reported in 2 participants (0.5%, spinal cord injury and ileus).

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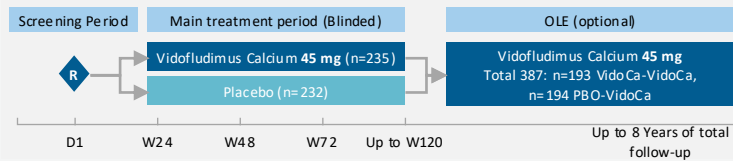
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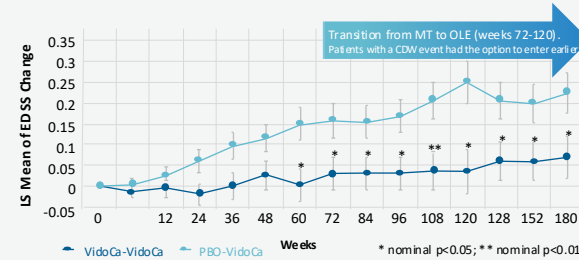
Supplemental Data

Supplemental Figure 1: Schematic of the study design



- During the main treatment (MT) period, participants in the PBO arm had the option to enter the OLE between weeks 72 and 120 and receive 45 mg vidofludimus calcium (PBO-vidofludimus calcium). Participants from the vidofludimus calcium arm also had the option to enter the OLE and continue treatment with vidofludimus calcium (vidofludimus calcium-vidofludimus calcium).
- If participants had a CDW event, they had the option to enter the OLE earlier than 72 weeks.

Supplemental Figure 2: Change from baseline in EDSS in patients entering the OLE



- Mean EDSS was comparable at MT baseline (5.12 vs 5.18) but diverged by OLE baseline (5.16 vs 5.38), with separation maintained through OLE week 48 (~week 180 in graph).
- Changes in EDSS were analyzed using a mixed model for repeated measures. Reported p-values are nominal.