

# VISIONARY-MS Blinded Interim Data Update



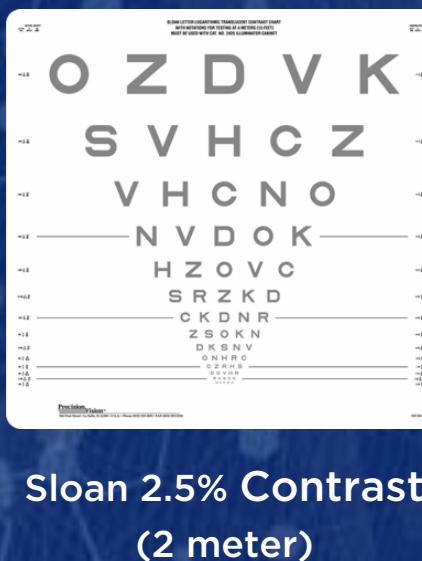
## Treatment of Visual Pathway Deficits In Chronic Optic Neuropathy for Assessment of Remyelination in Stable RMS

P113

H. Beadnall<sup>1</sup>, A. Klistorner<sup>3</sup>, M. Barnett<sup>3</sup>, R. Sergott<sup>4</sup>, A. Rynders<sup>2</sup>, K.S. Ho<sup>2</sup>, M. Mortenson<sup>5</sup>, R. Glanzman<sup>2</sup>, M. Hotchkin<sup>2</sup>

<sup>1</sup>Sydney Brain Mind Centre and Royal Prince Alfred Hospital, University of Sydney, Australia. <sup>2</sup>Clene Nanomedicine, Salt Lake City, UT. <sup>3</sup>Sydney Neuroimaging Analysis Centre, Sydney, Australia. <sup>4</sup>Annesley EyeBrain Center at Thomas Jefferson University Partnered with Wills Eye Hospital, Philadelphia, PA. <sup>5</sup>Clene Nanomedicine, North East, MD.

**Best Corrected Low Contrast Letter Acuity (OD/OS)**

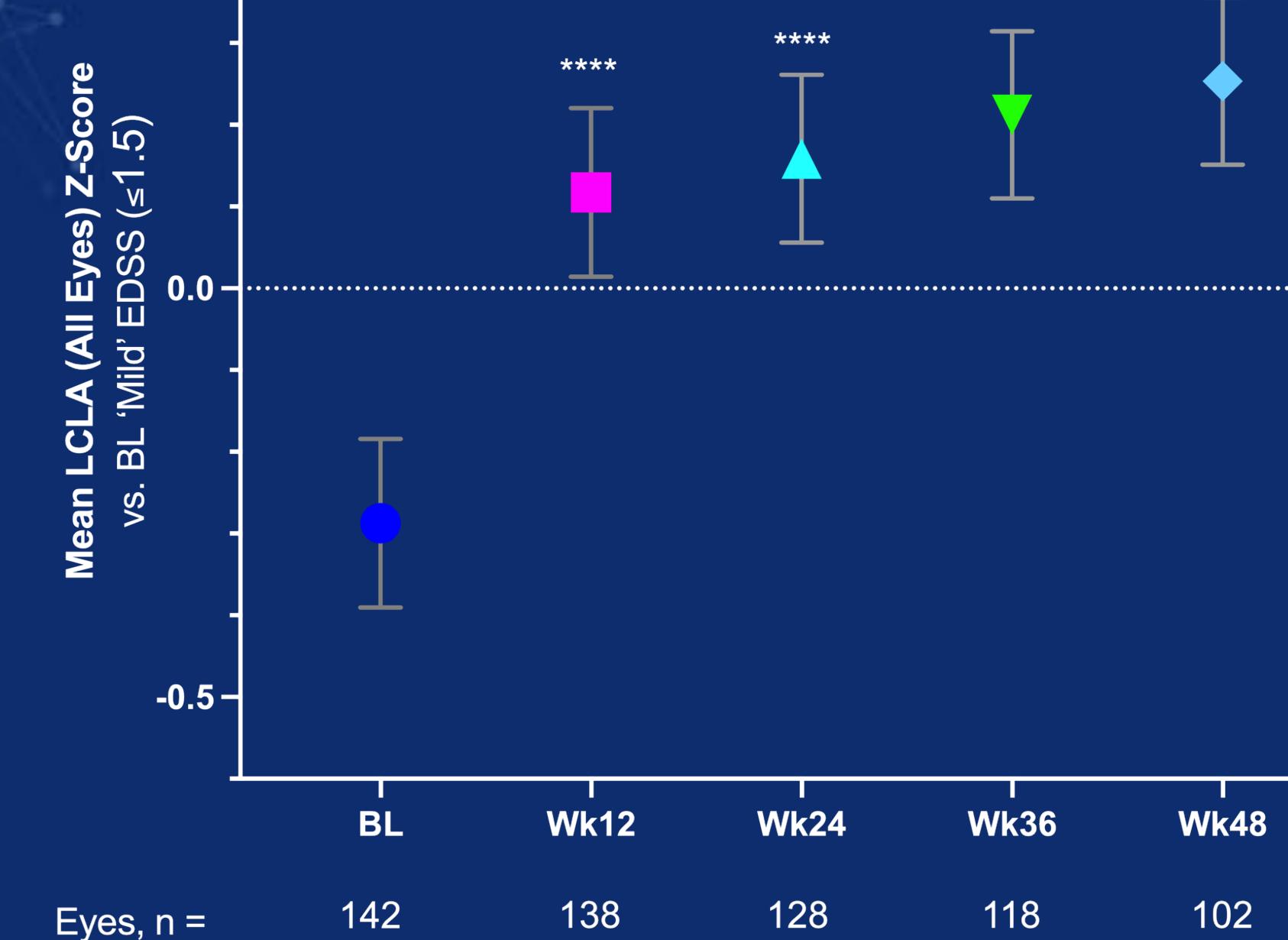


Sloan 2.5% Contrast  
(2 meter)

**LCLA  
(Primary Endpoint)**

**LCLA (All Eyes) Average Z-Score**  
14-February-2022 Data Cut, Preliminary Blinded Data  
(vs. 'Mild' EDSS [ $\leq 1.5$ ]; Mean  $\pm$  SEM)

Mixed-Effects Model, p = <0.0001



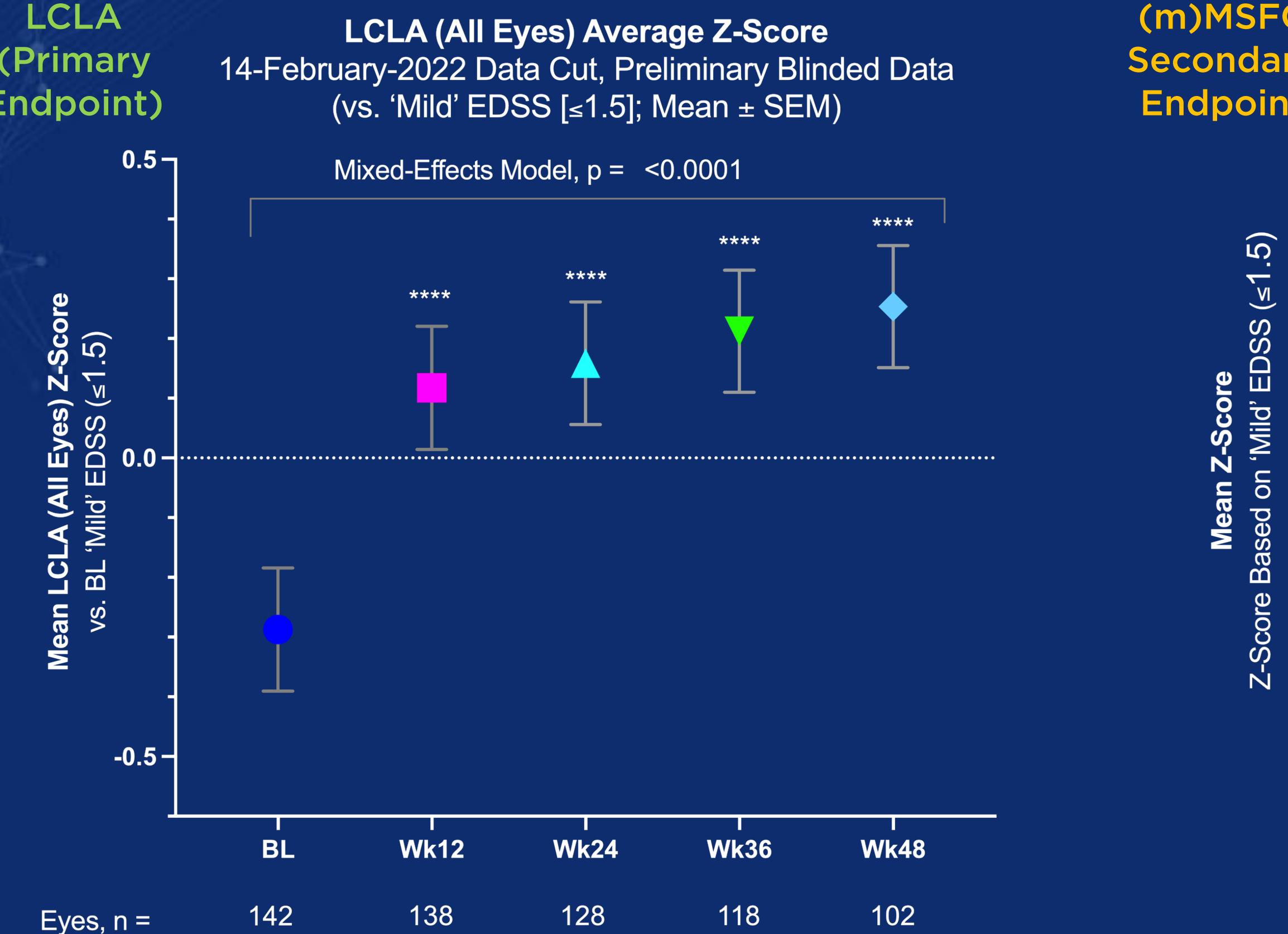
**Symbol Digit Modalities Test (Cognition)**



KEY

( - [ ] - > + =

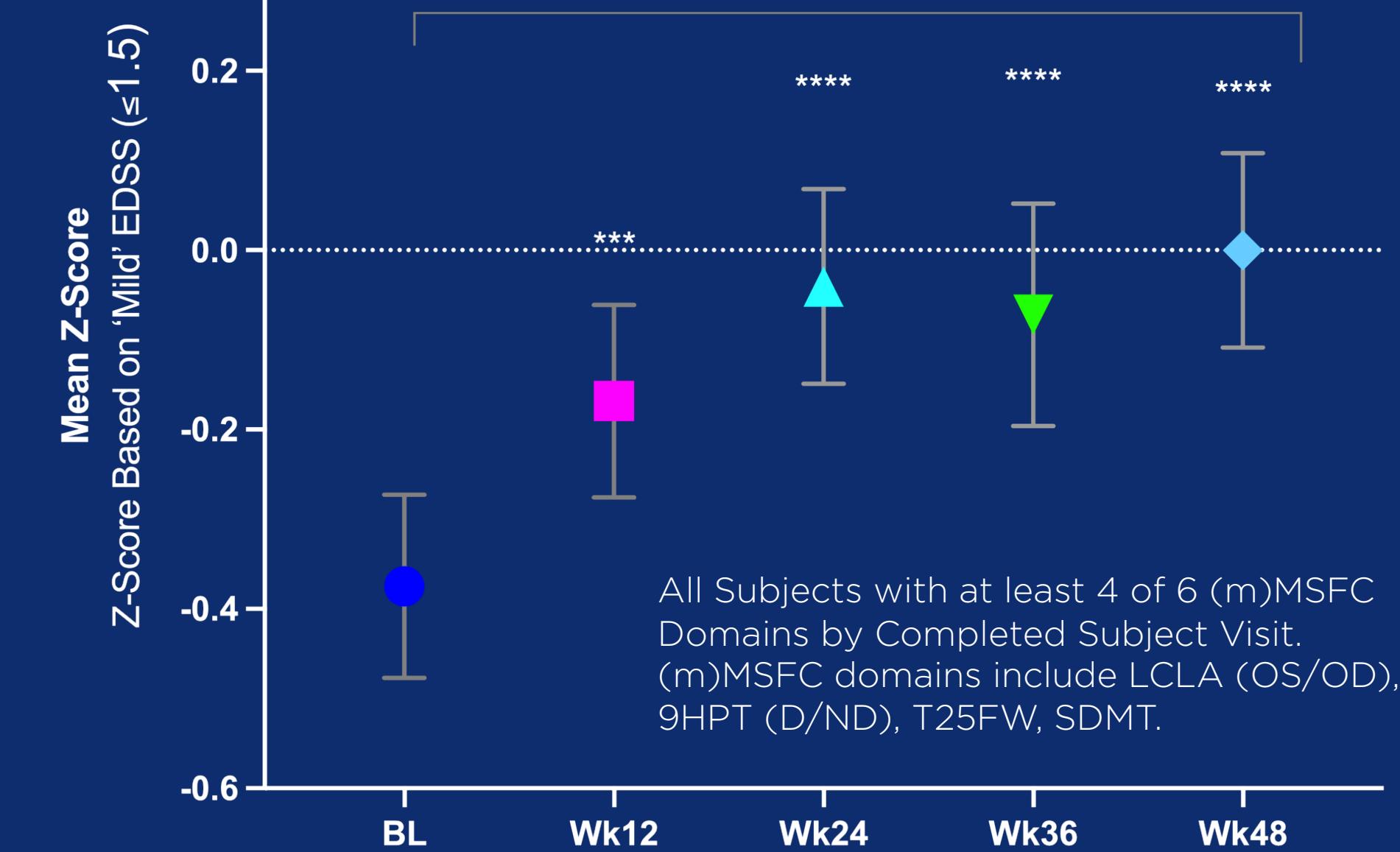
1 2 3 4 5 6 7 8 9



**(m)MSFC  
Secondary Endpoint**

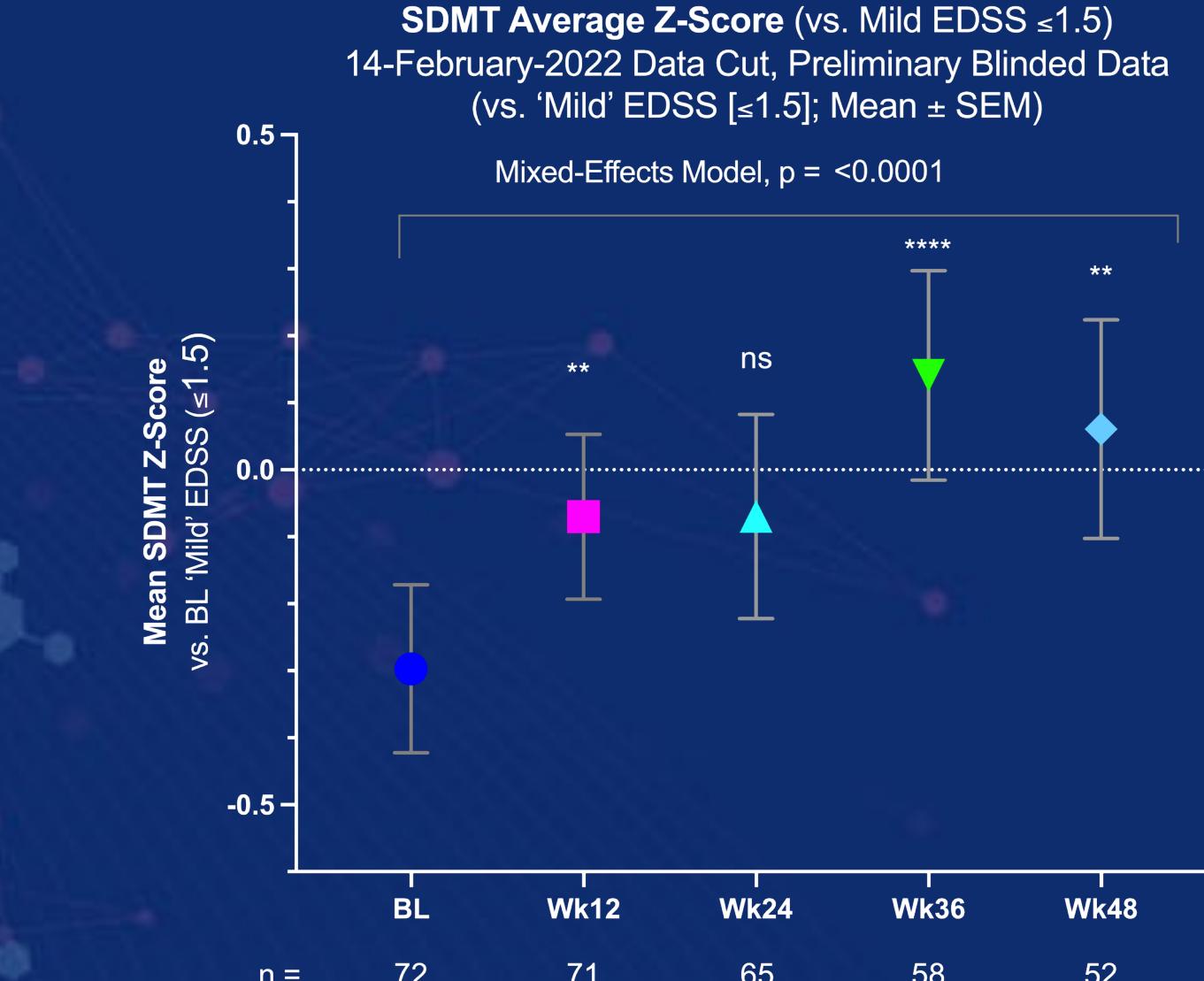
**(m)MSFC 6-Component Average Z-Score**  
14-February-2022 Data Cut, Preliminary Blinded Data  
(vs. 'Mild' EDSS [ $\leq 1.5$ ]; Mean  $\pm$  SEM)

Mixed-Effects Model, p = <0.0001

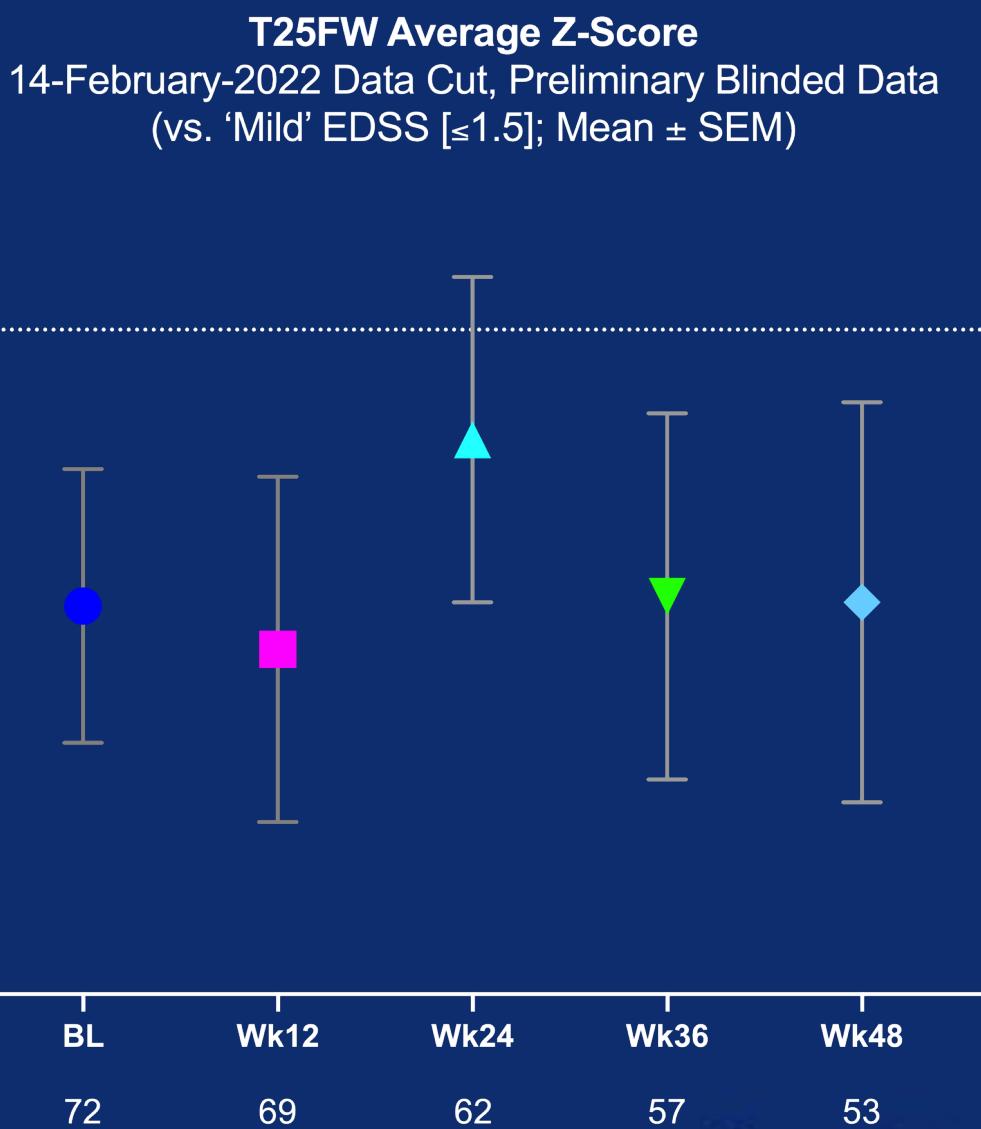
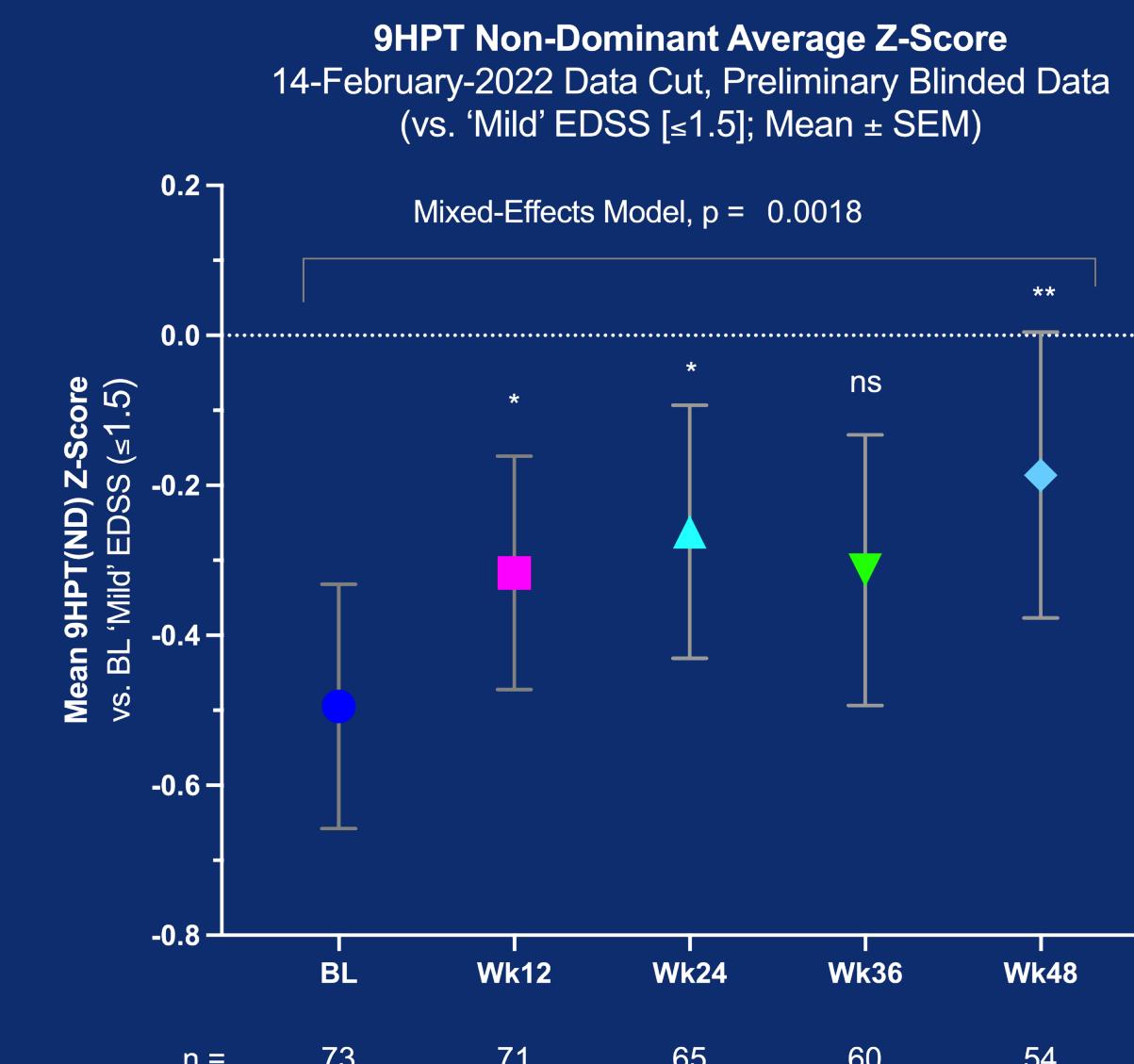
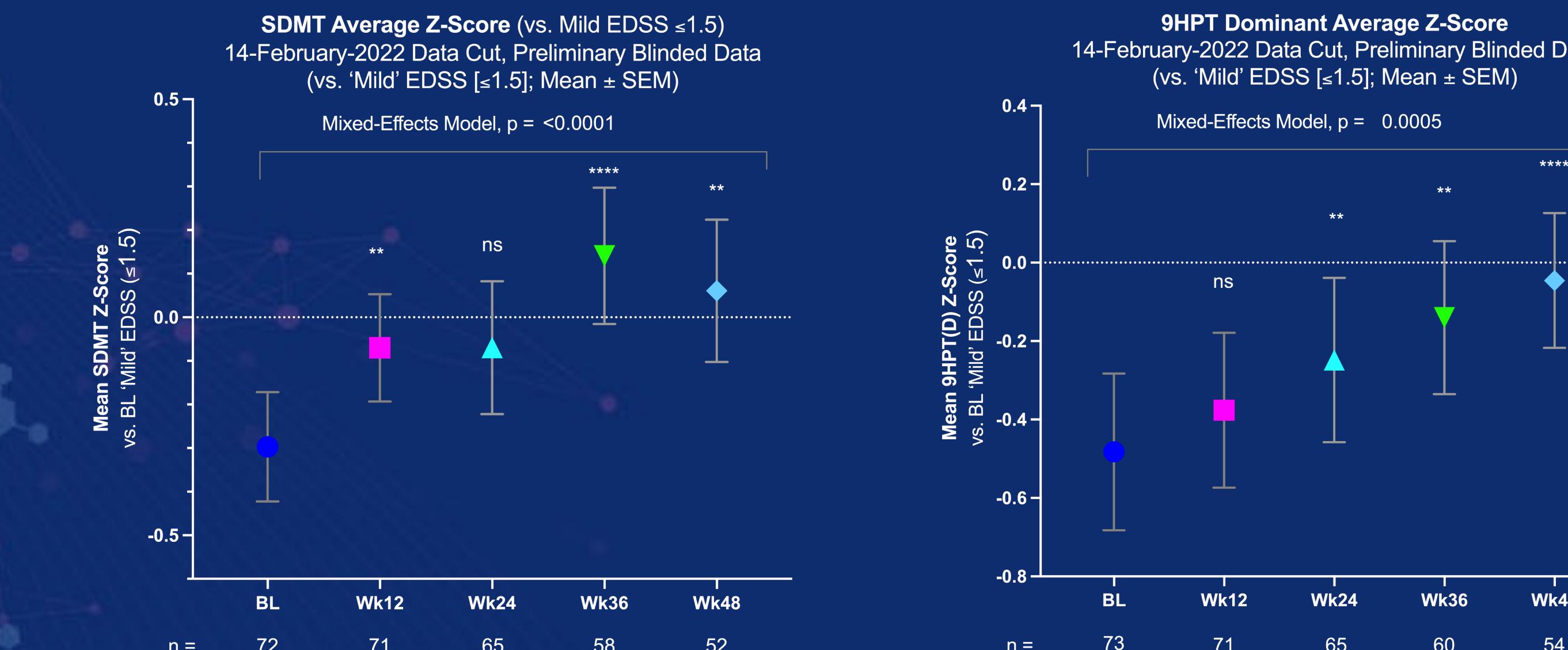


- Design:** Randomized Double-Blind Placebo Controlled Trial (1:1:1, 30mg, 15mg, Placebo)
- Safety:** No treatment related SAEs, TEAEs predominantly mild-to-moderate and transient
- Conclusion:** Blinded data show clinically relevant improvements across LCLA & modified-MSFC domains

**9-Hole Peg Test (D/ND)**



**Timed 25-Foot Walk**



Notes: Mixed Effects Model, Dunnett's test for multiplicity; \* p<0.05, \*\* p<0.01, \*\*\* p<0.001, \*\*\*\* p<0.0001. Z-Score based on Baseline value for EDSS with 'Mild' Severity (e.g., BL Low EDSS [ $\leq 1.5$ ]) for each domain. (m)MSFC is the modified MS Functional composite (Low contrast letter acuity (LCLA), 9-hole peg test (9HPT), Timed 25-foot walk (T25FW), and Symbol digit modalities test (SDMT)). All available data in EDC.