The LiBBY Trial

LIfe's end Benefits of cannaBidiol and tetrahYdrocannabinol Trial

Open-Label Extension Phase Topline Results

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With Gratitude to Libby Sofar whose experience with agitation in late-life inspired this study.

The LiBBY Study is funded by the National Institute on Aging (NIA) of the National Institutes of Health (NIH) and the Alzheimer's Association. It is being conducted by the NIH-funded Alzheimer's Clinical Trial Consortium (ACTC) and coordinated by the University of Southern California's Epstein Family Alzheimer's Therapeutic Research Institute (ATRI), Medical University of South Carolina, and Georgetown University.

The LiBBY Trial Topline Double-Blind Results were presented at AAIC on July 14, 2026

Session: P15271

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Key Inclusion and Exclusion Criteria- LiBBY DB

Inclusion Criteria

- 40 years of age or older
- Meets DSM-V criteria for Major Neurocognitive Disorder
- NPI-agitation subscale of 4 or above at Screening
- Meets at least one of the following requirements:
  - Currently enrolled in inpatient/outpatient hospice care
  - FAST Score of 6D or greater
  - ADEPT Score of 12 or greater
- Has a third-party clinician who is managing patient care
- Resides in a suitable environment (i.e., where research can successfully be conducted)

Exclusion Criteria

- Use of cannabinoids or other forms of marijuana in the 3 weeks prior to Baseline
- Known allergic reactions, adverse reactions, or hypersensitivity to cannabinoids and/or components of sesame oil
- Treatment with another investigational drug of other intervention within the previous 30 days or five half-lives of the investigational product, whichever is longer

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FAST= Functional Assessment Staging Tool
ADEPT = Advanced Dementia Prognostic Tool

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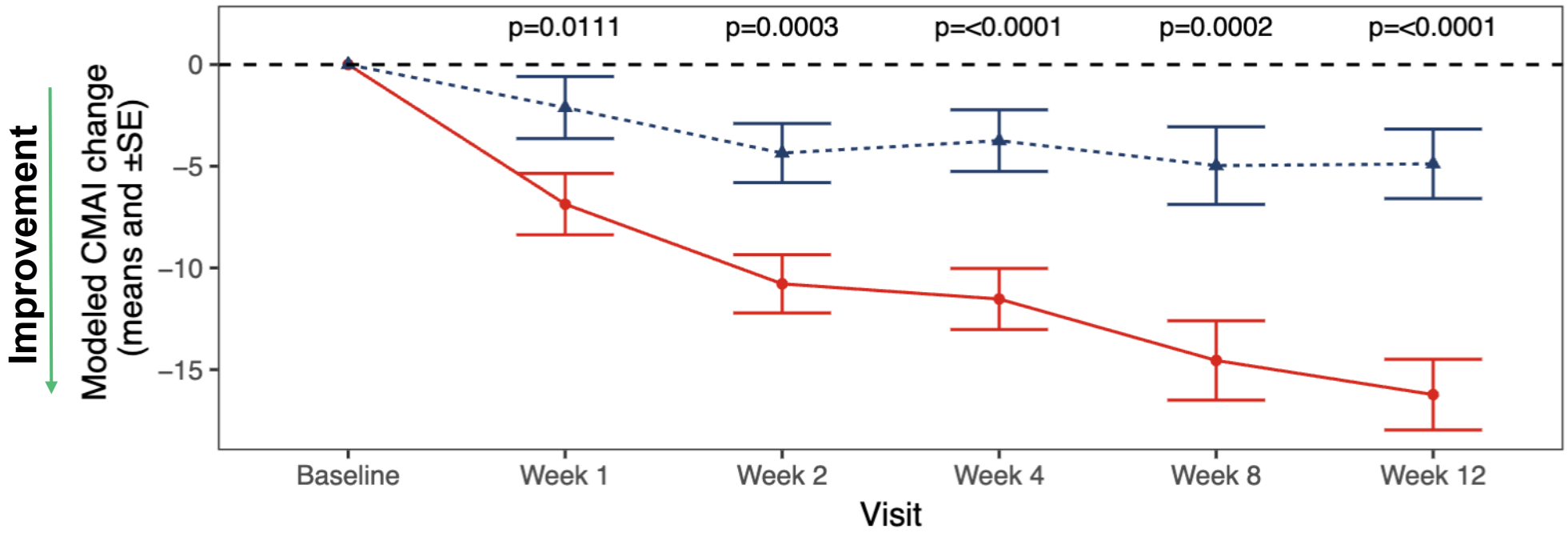
LiBBY DB Results: Primary Outcome: CMAI Frequency at week 2



T2:C100	57	56	56	55	50	47
Placebo	59	59	59	59	57	55

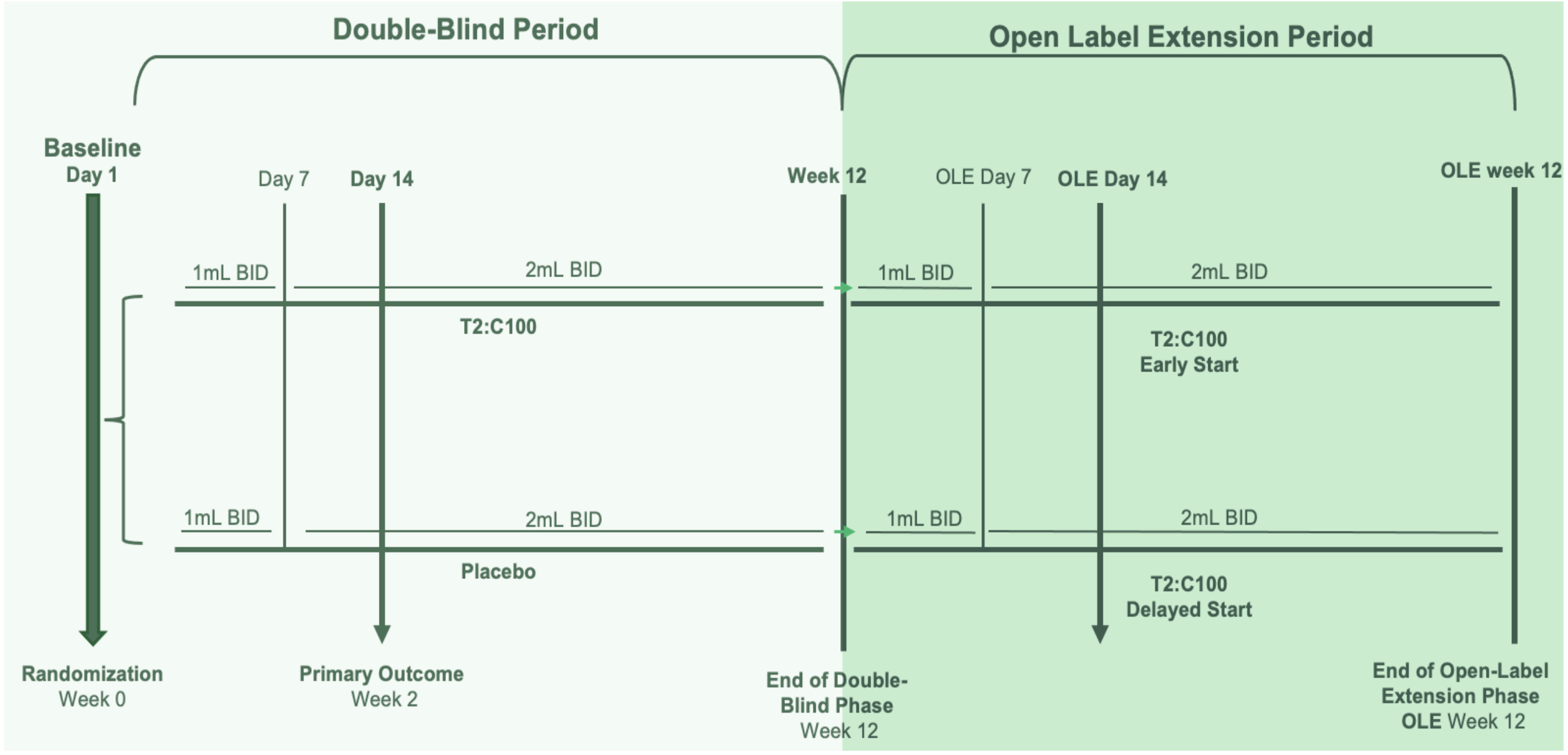
p value reflects the contrast between intervention arms derived from a MMRM model adjusted for the following covariates: hospice, treatment location, binary site, baseline score and baseline score*time.

Open-Label Extension: Rationale

- Offered voluntary access to the Investigational Product to all study participants who completed the Double-Blind phase of the study
- Provided additional data on long-term safety, tolerability, and efficacy of T2:C100
- The OLE was a 12-week period following the end of the DB
- Visits and assessments were scheduled at DB week12 and OLE weeks 1,2,4,8, and 12

Study Design

12-week, Phase 2, Multi-Center, Randomized, Double-blind, Parallel-group, Placebo-controlled study



Study Flow

	Randomized	Completed Double-Blind Phase	Started Open-Label Extension Phase	Completed Open-Label Extension Phase
T2:C100/T2:C100 Early Start	61	46	43	39
Placebo/T2:C100 Delayed Start	59	54	50	46

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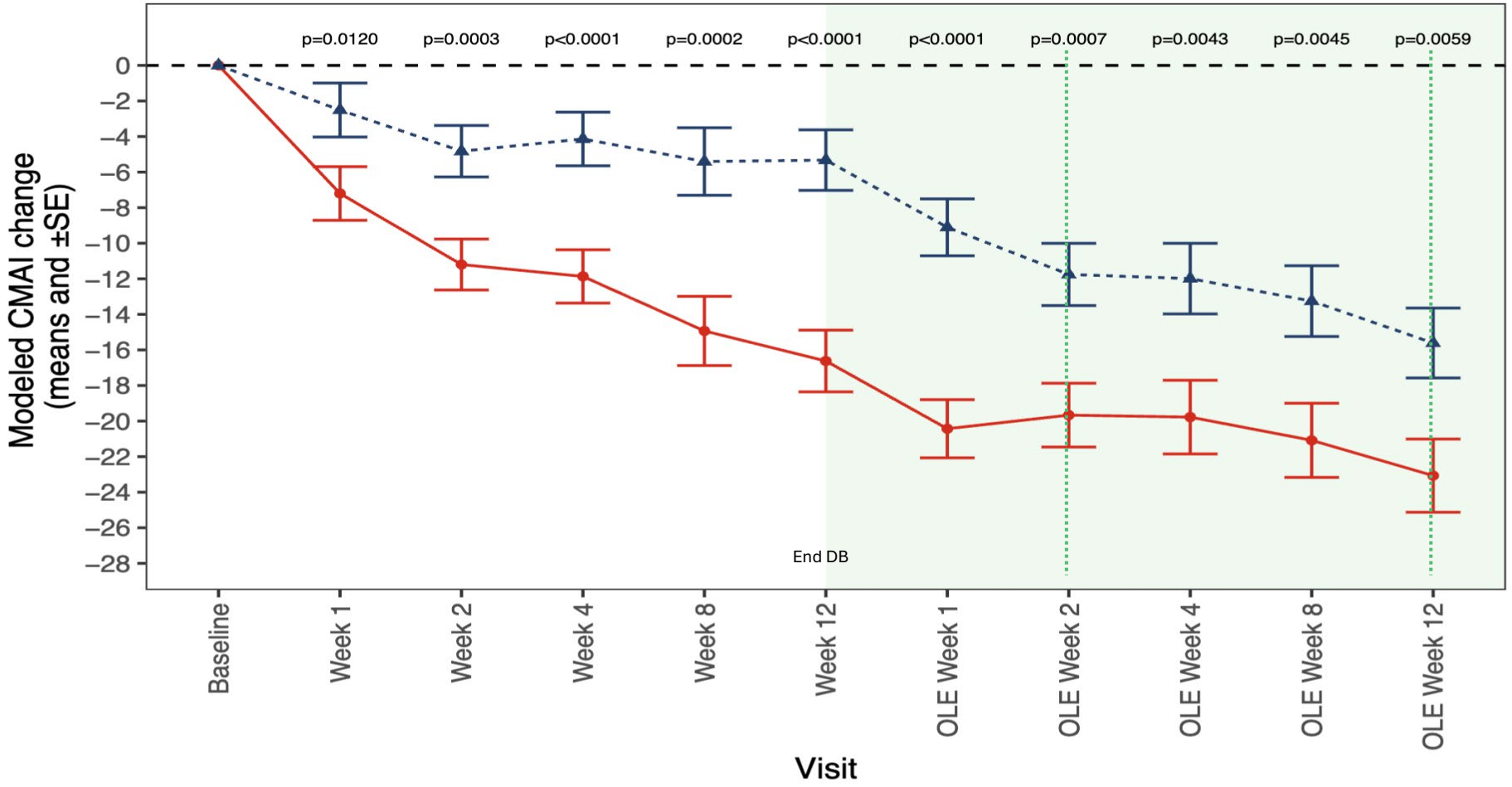
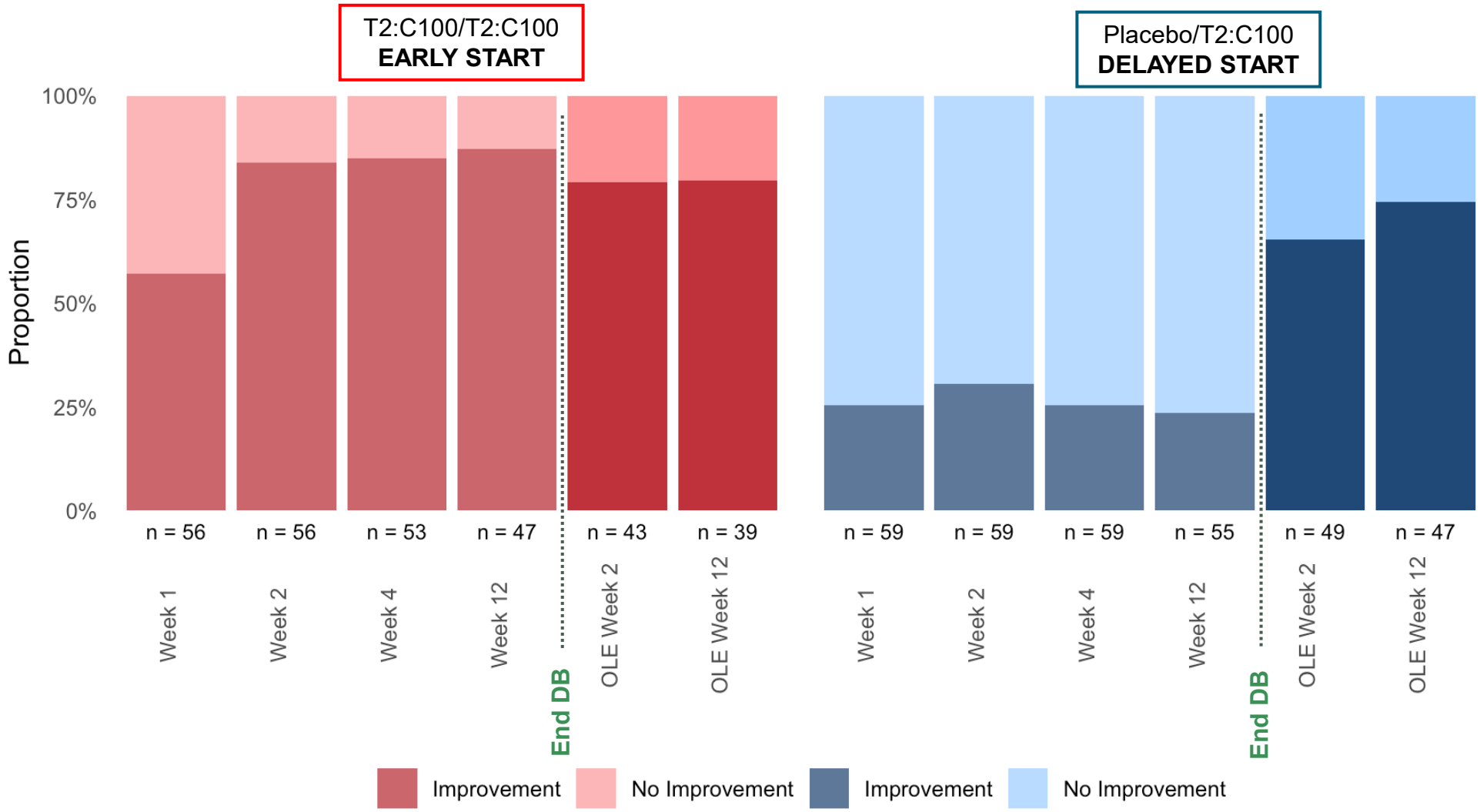
Topline OLE Results

OLE Primary outcome: CMAI Frequency over 24 weeks



T2:C100/T2:C100 **EARLY START**	57	56	56	55	50	47	42	43	41	41	39
Placebo/T2:C100 **DELAYED START**	59	59	59	59	57	55	50	49	49	48	47

Clinical Global Impression of Change in Behavior (CGIC-B)



OLE Treatment Emergent Adverse Events

	From OLE week 0 to OLE week 12	
	Early Start N = 43	**Delayed Start** N = 50
Number of subject who experienced at least one AE	**14 (32.6%)**	**23 (46%)**
Nervous system disorders	2 (4.7%)	11 (22%)
General disorders and administration site conditions	2 (4.7%)	6 (12%)
Infections and infestations	4 (9.3%)	4 (8%)
Psychiatric disorders	3 (6.9%)	5 (10%)
Gastrointestinal disorders	3 (6.9%)	4 (8%)
Injury, poisoning and procedural complications	3 (6.9%)	4 (8%)
Metabolism and nutrition disorders	2 (4.7%)	5 (10%)
Musculoskeletal and connective tissue disorders	2 (4.7%)	4 (8%)
Respiratory, thoracic and mediastinal disorders	3 (6.9%)	2 (4%)
Number of subject who experienced SAE at least once	**7 (16.3%)**	**3 (6%)**

Only SOC with overall percentages greater than 5% are presented

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Deaths: OLE - No difference between groups

	Early Start T2:C100 N = 43	Delayed Start Placebo N = 50	Difference of proportion (95% CI)
# (%) of Participants	3 (7%)	3 (6%)	1% (-12%, 10%)

Intervention	AE related to cause of Death
Early Start	Acute respiratory Failure
	Vascular dementia
	Respiratory distress
Delayed Start	Dementia Alzheimer's type
	Dehydration
	Ischemic stroke /Respiratory failure

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OLE Conclusions

- Provided support for the efficacy of the treatment
  - The delayed-start participants showed a substantial benefit of active treatment on the CMAI and the CGIC-B
- Early-start participants continued to improve on the CMAI with continued treatment
- No significant safety concerns were observed in the OLE

The data presented today is specific to the LiBBY trial population using the T2:C100 formulation and its exact delivery system and does not indicate the safety or efficacy of other THC:CBD formulations or recreational marijuana.

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