

# SUBCUTANEOUS LECANEMAB ADMINISTRATION IN AN ALZHEIMER'S DISEASE TREATMENT CENTER: REAL-WORLD CLINICAL OUTCOMES AND PATIENT EXPERIENCES

David Watson, Michael G. Neam, Mark Stafford, Cynthia Bouchard, Venessa Ranney, and Sydney Werner  
Alzheimer's Research and Treatment Center, Wellington, FL



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## Introduction

- Lecanemab is an anti-amyloid monoclonal antibody that selectively targets plaques and neurotoxic amyloid- $\beta$  (A $\beta$ ) protofibrils, which are more toxic than monomers or insoluble fibrils/plaque<sup>1-4</sup>
- In the phase 3 Clarity AD trial, lecanemab reduced markers of amyloid in early symptomatic Alzheimer's disease (AD; mild cognitive impairment [MCI] and mild AD) and slowed decline on endpoints of cognition and function at 18 months<sup>5</sup>
- In addition, benefits of lecanemab treatment can be maintained longer-term as demonstrated in the ongoing open-label extension (OLE) studies<sup>6-7</sup>
- In Clarity AD, lecanemab was associated with a relative preservation of health-related quality of life and less increase in caregiver burden<sup>8</sup>
- Given the chronic nature of the disease and need for ongoing treatment, IV maintenance dosing (10 mg/kg monthly) and an alternate weekly subcutaneous dosing has been approved in the United States
- Herein, we report the clinical efficacy data through 36 months at the largest enrolling US site and assessed experiences of patients and care partners from this site who transitioned to subcutaneous (SC) lecanemab

## Methods

- This retrospective cohort study analyzed Clinical Dementia Rating–Sum of Boxes (CDR-SB) data for 34 trial patients who transitioned to SC lecanemab after 18-month intravenous lecanemab treatment at the Alzheimer's Research and Treatment Center (ARTC) in Wellington, Florida
- A matched Alzheimer's Disease Neuroimaging Initiative (ADNI) cohort (N=352) served as a historical control beyond 18 months for a CDR-SB comparison in 28 patients
- Patients and/or their care partners were asked to complete a survey evaluating their experience with the subcutaneous formulation of lecanemab
- The survey included 10 single-choice questions using a Likert scale and one open-ended question to capture experiences with SC administration
- Survey questions were adapted from the Therapy Administration Satisfaction Questionnaire (TASQ-SC) © and the Patient Preference Questionnaire (PPQ)©. Surveys were completed by either patients (n=25) or care partners (n=9)

## Results

- The mean age of the SC lecanemab patients was 72.4 years (standard deviation, SD=7.8) (**Table 1**)
- Overall, 75% of patients had MCI and 25% of patients had mild AD
- APOE4 carriers comprised 64% of the population
- Mean baseline CDR-SB score of 2.39 (SD = 1.23)
- The baseline characteristics of the ADNI cohort closely matched the SC lecanemab patients (**Table 1**)

## Results (continued)

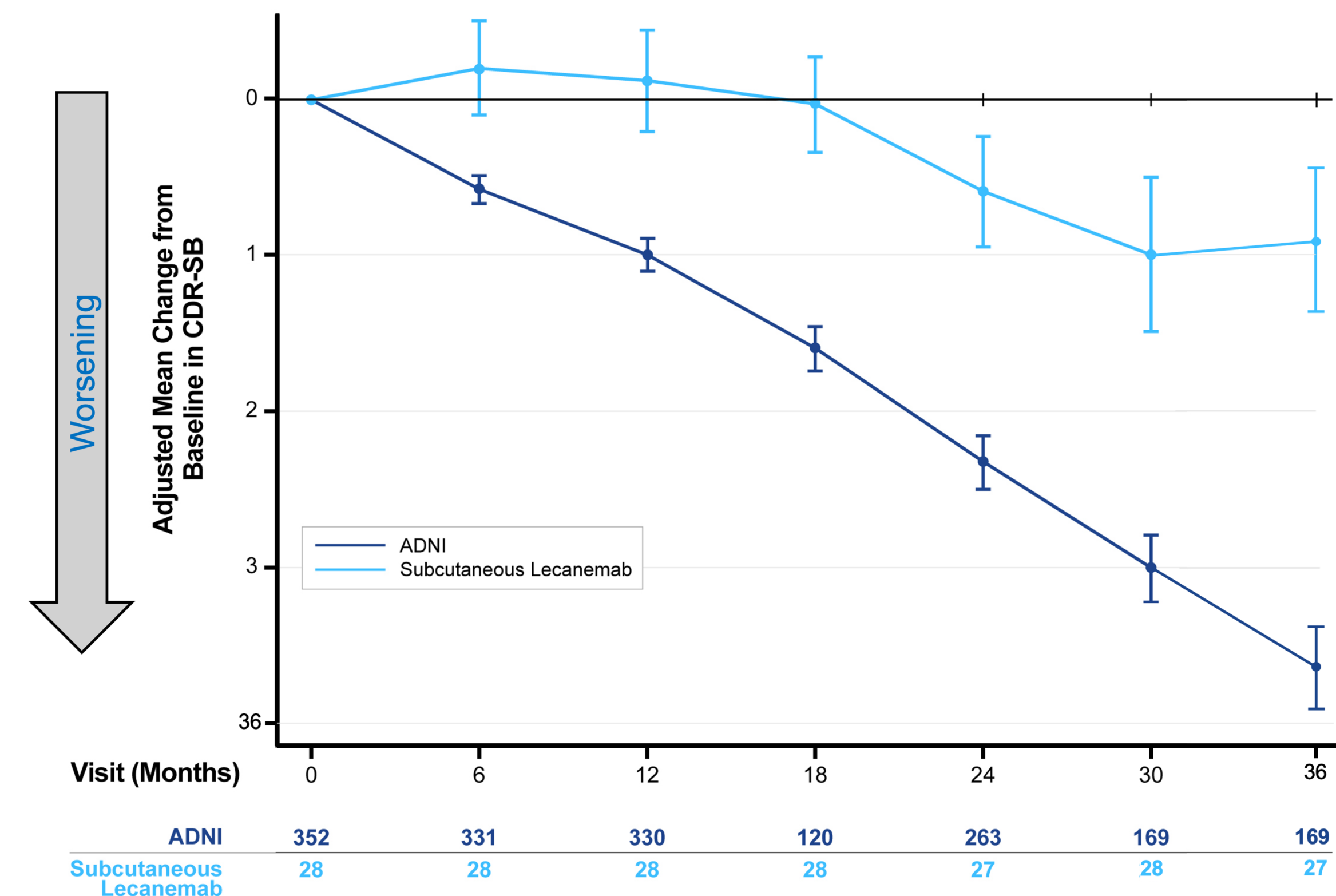
**Table 1.** Baseline Characteristics

|                            | Lecanemab Subcutaneous (N=28)* | ADNI Natural History Matched Cohort (N=352) |
|----------------------------|--------------------------------|---------------------------------------------|
| Age, mean years (SD)       | 72.4 (7.8)                     | 73.4 (7.4)                                  |
| AD Stage, %                |                                |                                             |
| MCI                        | 75%                            | 76%                                         |
| Mild AD                    | 25%                            | 24%                                         |
| APOE4 carrier status, %    | 64%                            | 70%                                         |
| Baseline CDR-SB, mean (SD) | 2.39 (1.23)                    | 2.29 (1.43)                                 |

\*Baseline characteristics for 28 of 34 patients that were included in the CDR-SB efficacy analysis.

- CDR-SB scores for the 28 lecanemab subcutaneous-treated patients demonstrated a continued slowing of cognitive decline compared to the matched ADNI cohort over 36 months (**Figure 1**)
- The increasing differences in the CDR-SB mean change from baseline observed at each timepoint with intravenous lecanemab treatment in the Core continued in the OLE at 36 months after patients transitioned to subcutaneous lecanemab following 18 months of intravenous lecanemab treatment

**Figure 1.** CDR-SB Results for Patients in Subcutaneous Lecanemab Analysis\*



\*For patients receiving subcutaneous lecanemab, there are 25 de novo subjects for which data is change from OLE baseline and 3 subjects who received intravenous lecanemab in the randomized Core phase of Clarity AD for which data is change from Clarity AD Core baseline. Of the 34 patients in our analysis, there are 3 subjects in Core LEC, 6 subjects in Core PBO, and 25 de novo subjects. Core LEC, Core PBO and de novo subjects used the same inclusion/exclusion criteria, but only Core LEC and de novo subjects started lecanemab just after enrolled to study. Core PBO was not included as they have 18 months no treatment duration.

- Survey responses demonstrated high satisfaction with the subcutaneous lecanemab administration (**Table 2**)
- Nearly all respondents reported very favorable or favorable experiences with treatment satisfaction (97%) and convenience (97%)

**Table 2.** Lecanemab Subcutaneous Survey Results

| Treatment Satisfaction             |                   |                     |                |                    |
|------------------------------------|-------------------|---------------------|----------------|--------------------|
| Very Satisfied                     | Satisfied         | Neither             | Dissatisfied   | Very Dissatisfied  |
| 88.2%                              | 8.8%              | 2.9%                | 0              | 0                  |
| Treatment Convenience              |                   |                     |                |                    |
| Very Convenient                    | Convenient        | Neither             | Convenient     | Very Convenient    |
| 88.2%                              | 8.8%              | 2.9%                | 0              | 0                  |
| Feel Restricted During Treatment   |                   |                     |                |                    |
| Not at All                         | A Little Bit      | Somewhat            | Very Much      | Extremely          |
| 100%                               | 0                 | 0                   | 0              | 0                  |
| Comfort with Self-Injection        |                   |                     |                |                    |
| Strongly Agree                     | Agree             | Neither             | Disagree       | Strongly Disagree  |
| 82.4%                              | 8.8%              | 2.9%                | 0              | 5.9%               |
| Confidence in Remembering Doses    |                   |                     |                |                    |
| Strongly Agree                     | Agree             | Neither             | Disagree       | Strongly Disagree  |
| 73.5%                              | 20.6%             | 0                   | 0              | 5.9%               |
| Help with Returning to Normal Life |                   |                     |                |                    |
| Strongly Agree                     | Agree             | Neither             | Disagree       | Strongly Disagree  |
| 73.5%                              | 11.8%             | 8.8%                | 5.9%           | 0                  |
| Bother from Time Required          |                   |                     |                |                    |
| Not at All Bothered                | A Little Bothered | Moderately Bothered | Very Bothered  | Extremely Bothered |
| 97.1%                              | 2.9%              | 0                   | 0              | 0                  |
| Gain/Loss of Time for Other Things |                   |                     |                |                    |
| Gained a Lot of Time               | Gained Some Time  | Neither             | Lost Some Time | Lost a Lot of Time |
| 64.7%                              | 23.5%             | 11.8%               | 0              | 0                  |
| Likelihood to Recommend            |                   |                     |                |                    |
| Definitely Yes                     | Probably Yes      | Not sure            | Probably Not   | Definitely Not     |
| 94.1%                              | 5.9%              | 0                   | 0              | 0                  |

- All patients preferred subcutaneous over intravenous dosing, citing quickness, ease, and comfort as the main reasons
- Most respondents expressed comfort with self-injection (91%) and confidence in remembering doses (94%), while 85% reported that treatment will help them return to normal life
- All participants indicated they would recommend SC treatment to others (94% definitely, 6% probably)
- No patients reported feeling restricted by treatment or burdened by the time required
- Subjects who transitioned from IV to SC had an option to go back to IV per Clarity AD OLE protocol, however, no subjects went back to IV

## Conclusions

- Patients treated with SC lecanemab sustained treatment through 36 months
- The SC lecanemab formulation was highly preferred by patients and care partners
- Patient and care partner feedback highlighted reduced treatment burden and strong acceptability

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