Lecanemab for Early Alzheimer’s Disease: Effectiveness and Value

Public Meeting — March 17, 2023

Meeting materials available at: https://icer.org/assessment/alzheimers-disease-2022/
Patient Experts

Doreen Monks, RN, MSN, Advocate

• No conflicts to disclose

Russ Paulsen, MA, Chief Operating Officer, UsAgainstAlzheimer’s

• UsAgainstAlzheimer’s receives funding from companies, including less than 25% from Eisai Co.
Clinical Experts

Victor Henderson, MD, MS, Professor of Epidemiology & Population Health and of Neurology, Stanford University

• No conflicts to disclose

Jason Karlawish, MD, Professor of Medicine, University of Pennsylvania

• Dr. Karlawish has received manufacturer support of research in the clinical area of this meeting.

• Dr. Karlawish has served as a site investigator for clinical trails sponsored by Eli Lilly & Co. and Biogen Inc.
“I get frustrated when people question my diagnosis – ‘oh you are fine and are just looking for attention’. I get frustrated when I can’t understand a joke and everyone else is laughing. I get frustrated when I don’t remember somebody, but they remember me – it’s mortifying…. It’s hard when I’m not sharp like I used to be.”

Person living with Alzheimer’s disease
Why Are We Here Today?

• What happens the day these treatments receive FDA approval?

• Questions about:
  • What are the risks and benefits?
  • How do new treatments fit into the evolving landscape?
  • What are reasonable prices and costs to patients, the health system, and the government?
  • What lessons are being learned to guide our actions in the future?
The Impact on Rising Health Care Costs for Everyone

Organizational Overview

- California Technology Assessment Forum (CTAF)
- Institute for Clinical and Economic Review (ICER)
Funding 2023

Nonprofit Foundations 65%
Life Science Contributions 15%
Health Plans and Provider Group Contributions 10%
ICER Analytics Subscribers 8%
Philanthropy/Other 2%

ICER Policy Summit and non-report activities only

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https://icer.org/who-we-are/independent-funding/
How Was the ICER Report Developed?

• Scoping with guidance from patients, clinical experts, manufacturers, and other stakeholders
• Internal ICER evidence analysis and cost-effectiveness modeling
• Public comment and revision
• UsAgainstAlzheimer’s provided initial feedback on the draft report
• Expert reviewers of the draft report
  • Victor Henderson, MD, MS, Professor, Stanford University
  • Jason Karlawish, MD, Professor, University of Pennsylvania
• How is the evidence report structured to support CTAF voting and policy discussion?
Value Assessment Framework: Long-Term Value for Money

- **Special Social/Ethical Priorities**
- **Benefits Beyond “Health”**
- **Total Cost Overall**
  - Including Cost Offsets
- **Health Benefits:**
  - Return of Function, Fewer Side Effects
- **Health Benefits:**
  - Longer Life
## Agenda

<table>
<thead>
<tr>
<th>Time (PT)</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00 am—9:20 am</td>
<td>Meeting Convened and Opening Remarks</td>
</tr>
<tr>
<td>9:20 am—10:00 am</td>
<td>Presentation of the Clinical Evidence</td>
</tr>
<tr>
<td>10:00 am—10:40 am</td>
<td>Presentation of the Economic Model</td>
</tr>
<tr>
<td>10:40 am —11:10 am</td>
<td>Public Comments and Discussion</td>
</tr>
<tr>
<td>11:10 am—11:50 am</td>
<td>Lunch Break</td>
</tr>
<tr>
<td>11:50 am—12:50 pm</td>
<td>CTAF Vote on Clinical Effectiveness and Value</td>
</tr>
<tr>
<td>12:50 pm—1:00 pm</td>
<td>Break</td>
</tr>
<tr>
<td>1:00 pm—2:30 pm</td>
<td>Policy Roundtable</td>
</tr>
<tr>
<td>2:30 pm—3:00 pm</td>
<td>Reflections from CTAF</td>
</tr>
<tr>
<td>3:00 pm</td>
<td>Meeting Adjourned</td>
</tr>
</tbody>
</table>
Presentation of the Clinical Evidence

Grace Lin, MD

Medical Director for Health Technology Assessment, ICER

Professor of Medicine and Health Policy, University of California, San Francisco
Key Collaborators

- Abigail Wright, PhD, MSc, Senior Research Lead, Evidence Synthesis, ICER
- Serina Herron-Smith, BA, Associate Research Manager, ICER
- Foluso Agboola, MBBS, MPH, Vice President of Research, ICER

Disclosures:

We have no conflicts of interest relevant to this report.
Alzheimer’s Disease
Impact of Illness

6.5 million cases in the United States

11 million caregivers provide 16 billion hours of care

Medical costs: $321 B
Caregiving costs: $272 B
Stages and Symptoms of AD

Preclinical AD
- No symptoms
- ApoE ε4+
- Amyloid plaques

MCI due to AD
- Very mild symptoms that do not interfere with everyday activities
- Memory loss
- Impaired judgment

Mild
- Symptoms interfere with some everyday activities
- Language problems
- Mood swings
- Personality changes

Moderate
- Symptoms interfere with many everyday activities
- Unable to recall new information
- Long-term memory loss
- Wandering
- Agitation, aggression
- Assistance with ADLs

Severe
- Symptoms interfere with most everyday activities
- Gait instability
- Incontinence
- May be bedridden
- Unable to perform ADLs
- Placement in long-term care


Living with Alzheimer’s: Insights from Patients and Caregivers

- Lack of cohesive care after diagnosis
- Coping with diagnosis and changes in life
- Caregiver impact
- Health inequities
- Fully capturing patient-important outcomes

Challenges of living with AD
Alzheimer's Disease
Treatment Options

Non-Pharmacologic Treatment
- Environmental manipulation
- Family support
- Prevention of other comorbidities

Symptomatic Treatment
- Cholinesterase inhibitors (e.g., donepezil)
- NMDA Receptor Antagonist (e.g., memantine)
- Antioxidants (e.g., selegiline)

Disease-Modifying Treatment
- Anti-amyloid antibodies

NMDA: N-methyl-D-aspartate
Clinical Evidence
Phase III RCT
N=1795
• MCI due to AD (62%) and mild AD
• Mean age: 71.2 y
• ApoE ε4+: 69%
• 77% White, 17% Asian, 12.4% Hispanic, Black 2.5%
• Baseline CDR-SB 3.2 (SD 1.34)

10 mg/kg IV lecanemab every two weeks
Follow-up at 18 months (Complete)
Open-label extension up to 69 months (Ongoing)

Placebo (Supportive care)
Follow-up at 18 months (Complete)

van Dyck et al. 2022

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Key Outcomes

• Primary outcome: Clinical Dementia Rating-Sum of Boxes (CDR-SB)
  • Measures 6 domains of cognition and function
  • Score 0-18, higher scores = more severe disease

• Secondary outcomes:
  • Cognitive and Functional Scales (e.g., ADAS-Cog14, ADCS-MCI-ADL, ADCOMS)
  • Health-Related Quality of Life (e.g., EQ-5D-5L, QOL-AD, and Zarit Burden Interview)
  • Biomarkers including amyloid, p-tau, t-tau (PET and CSF)
Beta-amyloid Levels by PET at 18 Months

B Amyloid Burden on PET

Less amyloid

Adjusted Mean Change from Baseline (centiloids)

Placebo

Lecanemab

P<0.001 at 18 mo

No. of Participants

<table>
<thead>
<tr>
<th></th>
<th>Lecanemab</th>
<th>354</th>
<th>296</th>
<th>275</th>
<th>276</th>
<th>210</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Patients</td>
<td>Placebo</td>
<td>344</td>
<td>303</td>
<td>286</td>
<td>259</td>
<td>205</td>
</tr>
</tbody>
</table>

Amyloid-negative (<30 CL) patients at 18 months:

Lecanemab: 32.4%
Placebo: 7.8%

CDR-SB at 18 Months

Worsening

Adjusted Mean Change from Baseline

P<0.001 at 18 mo

Visit (mo)

% Slowing of Decline | Mean Difference vs. Placebo
--- | ---
27% | -0.45 (95% CI: -0.67 to -0.23)

No. of Participants

<table>
<thead>
<tr>
<th></th>
<th>Lecanemab</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>859</td>
<td>875</td>
</tr>
<tr>
<td>3</td>
<td>824</td>
<td>849</td>
</tr>
<tr>
<td>6</td>
<td>798</td>
<td>828</td>
</tr>
<tr>
<td>9</td>
<td>779</td>
<td>813</td>
</tr>
<tr>
<td>12</td>
<td>765</td>
<td>779</td>
</tr>
<tr>
<td>15</td>
<td>738</td>
<td>767</td>
</tr>
<tr>
<td>18</td>
<td>714</td>
<td>757</td>
</tr>
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</table>

## Health-Related Quality of Life Outcomes

<table>
<thead>
<tr>
<th>Quality of Life Measure</th>
<th>% Less Decline vs. Placebo</th>
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</thead>
<tbody>
<tr>
<td>EQ-5D-5L (Participant)</td>
<td>49%</td>
</tr>
<tr>
<td>QOL-AD (Participant)</td>
<td>56%</td>
</tr>
<tr>
<td>QOL-AD (Caregiver)</td>
<td>23%</td>
</tr>
<tr>
<td>Zarit Burden Interview (Caregiver)</td>
<td>38%</td>
</tr>
</tbody>
</table>

EQ-5D-5L: European Quality of Life – 5 dimensions (5 level version), QOL-AD: Quality of Life in Alzheimer’s Disease

Note: All were significant at p<0.05.
Key Secondary Cognitive Outcomes at 18 Months

All differences were statistically significant compared with placebo
Biomarker Outcomes at 18 Months (Preliminary)

- Statistically significant reductions in CSF t-tau, CSF and plasma p-tau in lecanemab group versus placebo.

- MRI Outcomes:
  - Less atrophy in hippocampal volume
  - Greater decrease in whole brain volume and greater increase in ventricular volume
Harms

- Amyloid-related imaging abnormalities (ARIA)
  - ARIA-E: 12.6% in lecanemab, 1.7% in placebo
    - Symptomatic ARIA-E: 2.8% in lecanemab, 0% in placebo
    - Mostly mild-moderate in severity, occurred early and resolved within 4 months
  - ARIA-H: 17.3% in lecanemab, 9% in placebo
    - Few symptomatic cases
    - More likely to co-occur with ARIA-E in lecanemab
    - More common in ApoE ε4, especially homozygotes
- Three reported deaths in OLE related to hemorrhage, potentially ARIA
- Discontinuation due to AEs: 6.9% in lecanemab and 2.9% in placebo
Controversies and Uncertainties

| Correlation Between Amyloid Clearance and Cognition | • Inconsistent benefit across drugs  
• Lack of data at the individual patient level  
• 7% of placebo group were amyloid “negative” at end of trial |
| Clinical Significance of Results | • Changes may not reach minimum clinically important difference for cognitive measures  
• Differences in outcomes by subgroup |
| Generalizability | • Clinical trial population younger, less diverse, fewer comorbidities than U.S. AD population |
| Safety | • Real-world monitoring of ARIA  
• Risk of cerebral hemorrhage with use of anticoagulants |
Potential Other Benefits and Contextual Considerations

- Delay in progression impacts both patient and caregiver abilities to achieve major life goals - e.g., work, education, family

- Complexity of treatment (biweekly IV infusions + potential monitoring for ARIA) may be significant burden

- Effective treatment could potentially decrease health inequities
  - African American and Hispanic patients tend to be underdiagnosed and diagnosed later
Public Comments Received

- Minimum clinically important difference for CDR-SB is debatable and applies to individual changes, not aggregate changes
- Risk of ARIA is overstated
- Disproportionate impact of disease on both persons with dementia and their caregivers in African American community
  - Later diagnosis, more severe symptoms
  - Greater caregiving burden
  - Underrepresentation in clinical trials
Summary

• Lecanemab shows statistically significant slowing of cognitive decline over 18 months of treatment, but questions about clinical significance remain

• ARIA remains a concern
  • 3 deaths in OLE potentially related to anticoagulation, ARIA

• Clinical trial results may not be generalizable to some populations
  • Underrepresentation of African Americans, older patients (>85) in trial
### ICER Evidence Rating for Lecanemab

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comparator</th>
<th>Evidence Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecanemab</td>
<td>Supportive care</td>
<td>P/I</td>
</tr>
</tbody>
</table>
Questions?
Presentation of the Economic Model

Melanie D. Whittington, PhD, MS
Director of Health Economics
Institute for Clinical and Economic Review
Disclosures

No conflicts to disclose defined as more than $10,000 in health care company stock or more than $5,000 in honoraria or consultancies relevant to this report during the previous year from health care manufacturers or insurers.
Objective

Estimate the lifetime cost effectiveness of lecanemab in addition to supportive care as compared to supportive care alone for the treatment of early Alzheimer’s disease.
Methods Overview

• **Model**: Markov Model

• **Setting**: United States

• **Perspective**: Health Care Sector and Modified Societal Perspective

• **Time Horizon**: Lifetime

• **Discount Rate**: 3% per year (costs and outcomes)

• **Cycle Length**: 1 year

• **Primary Outcomes**: cost; quality-adjusted life years (QALYs); equal value life years (evLYs); life years (LYs); years in the community setting
Model Schematic
Population

• The starting population for the economic evaluation included adults with early AD, defined as MCI due to AD or mild AD

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age, years</td>
<td>71 years</td>
</tr>
<tr>
<td>Percent Female, %</td>
<td>52%</td>
</tr>
<tr>
<td>Clinical Stage, %</td>
<td></td>
</tr>
<tr>
<td>MCI Due to AD</td>
<td>55%</td>
</tr>
<tr>
<td>Mild AD</td>
<td>45%</td>
</tr>
<tr>
<td>Setting of Care, %</td>
<td></td>
</tr>
<tr>
<td>Community</td>
<td>92%</td>
</tr>
<tr>
<td>Long-Term Care</td>
<td>8%</td>
</tr>
</tbody>
</table>

AD: Alzheimer’s disease, MCI: mild cognitive impairment
Key Model Assumptions

• Lecanemab was effective at slowing the progression of disease while a patient had MCI due to AD or mild AD.

• Patients stopped receiving lecanemab treatment once they reached moderate AD.

• No clinical benefit was assumed after a patient stopped treatment.

• All occurrences of ARIA and its associated consequences were modeled in the first year of treatment.
## Key Model Inputs: Effectiveness on Disease Progression

<table>
<thead>
<tr>
<th>Health State</th>
<th>Lecanemab</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCI due to AD</td>
<td>0.69</td>
</tr>
<tr>
<td>Mild AD</td>
<td>0.69</td>
</tr>
<tr>
<td>Moderate AD</td>
<td>1.00</td>
</tr>
<tr>
<td>Severe AD</td>
<td>1.00</td>
</tr>
</tbody>
</table>

AD: Alzheimer's disease, MCI: mild cognitive impairment
# Key Model Inputs: Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Lecanemab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of any ARIA</td>
<td>21.5%</td>
</tr>
<tr>
<td>Probability of symptomatic ARIA</td>
<td>3.5%</td>
</tr>
<tr>
<td>Probability of AE-related discontinuation</td>
<td>6.9%</td>
</tr>
</tbody>
</table>

AE: adverse event, ARIA: amyloid-related imaging abnormalities
# Key Model Inputs: Health State Disutilities

<table>
<thead>
<tr>
<th>Health State</th>
<th>Patient</th>
<th>Caregiver</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Community</td>
<td>LTC</td>
</tr>
<tr>
<td>MCI due to AD</td>
<td>-0.17</td>
<td>-0.17</td>
</tr>
<tr>
<td>Mild AD</td>
<td>-0.22</td>
<td>-0.19</td>
</tr>
<tr>
<td>Moderate AD</td>
<td>-0.36</td>
<td>-0.42</td>
</tr>
<tr>
<td>Severe AD</td>
<td>-0.53</td>
<td>-0.59</td>
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</tbody>
</table>

AD: Alzheimer’s disease; LTC: long-term care
### Key Model Inputs: Cost Inputs

<table>
<thead>
<tr>
<th>Cost Input</th>
<th>Cost</th>
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</thead>
<tbody>
<tr>
<td>Annual Wholesale Acquisition Cost</td>
<td>$26,500</td>
</tr>
<tr>
<td>MRI Unit Cost</td>
<td>$261</td>
</tr>
<tr>
<td>IV Administration Unit Cost</td>
<td>$78</td>
</tr>
</tbody>
</table>

IV: intravenous; MRI: magnetic resonance imaging
Results
Base-Case Results: Lifetime Model Outcomes

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Intervention Cost*</th>
<th>Total Cost</th>
<th>Life Years</th>
<th>QALYs</th>
<th>evLYs</th>
<th>Years in the Community</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecanemab</td>
<td>$109,000</td>
<td>$489,000</td>
<td>6.23</td>
<td>3.84</td>
<td>3.96</td>
<td>4.20</td>
</tr>
<tr>
<td>Supportive Care</td>
<td>$0</td>
<td>$363,000</td>
<td>5.77</td>
<td>3.34</td>
<td>3.34</td>
<td>3.69</td>
</tr>
</tbody>
</table>

QALYs: quality-adjusted life years, evLYs: equal value of life years
*Doesn’t include provider-administered mark-up, monitoring costs, or administration costs.
Base-Case Results: Lifetime Model Outcomes

### Health Care Sector Perspective

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Intervention Cost*</th>
<th>Total Cost</th>
<th>Life Years</th>
<th>QALYs</th>
<th>evLYs</th>
<th>Years in the Community</th>
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<td>4.20</td>
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<tr>
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<td>$0</td>
<td>$363,000</td>
<td>5.77</td>
<td>3.34</td>
<td>3.34</td>
<td>3.69</td>
</tr>
</tbody>
</table>

### Modified Societal Perspective

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Intervention Cost*</th>
<th>Total Cost</th>
<th>Life Years</th>
<th>QALYs</th>
<th>evLYs</th>
<th>Years in the Community</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecanemab</td>
<td>$109,000</td>
<td>$790,000</td>
<td>6.23</td>
<td>3.49</td>
<td>3.64</td>
<td>4.20</td>
</tr>
<tr>
<td>Supportive Care</td>
<td>$0</td>
<td>$670,000</td>
<td>5.77</td>
<td>2.98</td>
<td>2.98</td>
<td>3.69</td>
</tr>
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QALYs: quality-adjusted life years, evLYs: equal value of life years

*Doesn't include provider-administered mark-up, monitoring costs, or administration costs.
Base-Case Incremental Results

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Cost per QALY Gained</th>
<th>Cost per evLY Gained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Care Sector</td>
<td>$254,000</td>
<td>$204,000</td>
</tr>
<tr>
<td>Modified Societal</td>
<td>$236,000</td>
<td>$183,000</td>
</tr>
</tbody>
</table>

QALYs: quality-adjusted life years, evLYs: equal value of life years
Sensitivity Analyses

- One-way sensitivity analyses
  - Main driver: Hazard ratio on slowing progression of disease

- Probabilistic sensitivity analyses

<table>
<thead>
<tr>
<th>Perspective</th>
<th>$50,000 per evLYG</th>
<th>$100,000 per evLYG</th>
<th>$150,000 per evLYG</th>
<th>$200,000 per evLYG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Care Sector</td>
<td>0%</td>
<td>0%</td>
<td>11%</td>
<td>50%</td>
</tr>
<tr>
<td>Modified Societal</td>
<td>0%</td>
<td>1%</td>
<td>25%</td>
<td>63%</td>
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</table>

evLYG: equal value life years gained
## Scenario Analyses

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Base Case ($/evLYG)</th>
<th>Treatment Stop at Severe ($/evLYG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Care Sector</td>
<td>$204,000</td>
<td>$226,000</td>
</tr>
<tr>
<td>Modified Societal</td>
<td>$183,000</td>
<td>$211,000</td>
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</table>

evLYG: equal value life years gained
Limitations

• Confidence interval for the hazard ratio on the progression to the next stage of dementia was not available.

• Utility evidence is from a study published more than 20 years ago.
Comments Received

• Use a patient-level simulation model like AD ACE
• Use a threshold above common thresholds
• Patients with Alzheimer’s disease have more than one caregiver
Conclusions

• At the current wholesale acquisition cost, lecanemab exceeds commonly cited cost-effectiveness thresholds.

• The cost-effectiveness findings are primarily driven by the effectiveness of lecanemab at slowing the progression of disease.
Questions?
Public Comment and Discussion
## Manufacturer Public Commenters

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Title</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael Irizarry, MD, MPH</td>
<td>Senior Vice President, Clinical Research, Alzheimer’s Disease and Brain Health</td>
<td>Eisai Co., Ltd</td>
</tr>
<tr>
<td>Katie Herren, PharmD, MS</td>
<td>Senior Director, US Customer Engagement</td>
<td>Eli Lilly &amp; Co.</td>
</tr>
</tbody>
</table>
Michael Irizarry, MD, MPH
Senior Vice President, Clinical Research, Alzheimer’s Disease and Brain Health, Eisai Co., Ltd

Conflicts of Interest:

• Dr. Irizarry is a full-time employee of Eisai Co., Ltd
Conflicts of Interest:

- Dr. Herren is a full-time employee of Eli Lilly & Co.
## Patient Public Commenters

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Title</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russ Paulsen, MA</td>
<td>Chief Operating Officer</td>
<td>UsAgainstAlzheimer's</td>
</tr>
<tr>
<td>Susan Peschin, MHS</td>
<td>President &amp; CEO</td>
<td>Alliance for Aging Research</td>
</tr>
<tr>
<td>James Taylor, MBA</td>
<td>President &amp; CEO</td>
<td>Voices of Alzheimer's</td>
</tr>
</tbody>
</table>
Conflicts of Interest:

- UsAgainstAlzheimer’s receives funding from companies, including less than 25% from Eisai Co.
Conflicts of Interest:

- The Alliance for Aging Research receives more than 25% of its funding from health care companies.
Conflicts of Interest:

• Voices of Alzheimer’s receives more than 25% of its funding from health care companies including 25% from Eisai Co. and 25% from Eli Lilly & Co.

• Voices of Alzheimer’s collaborated with High Lantern Group in developing their statement.
Lunch

Meeting will resume at 11:50 am PT
Voting Questions
Clinical Evidence Questions
Patient population for all questions: Adults with early Alzheimer's disease (i.e., Mild Cognitive Impairment due to Alzheimer's disease and mild Alzheimer's dementia).

1. Is the evidence adequate to demonstrate that the net health benefit of lecanemab added to supportive care is superior to that provided by supportive care alone?

A. Yes

B. No
Contextual Considerations and Potential Other Benefits or Disadvantages
When making judgements of overall long-term value for money, what is the relative priority that should be given to any effective treatment for early Alzheimer’s disease with evidence of Alzheimer’s disease pathology, on the basis of the following contextual considerations:

2. Acuity of need for treatment of individual patients based on short-term risk of death or progression to permanent disability

A. Very low priority
B. Low priority
C. Average priority
D. High priority
E. Very high priority
When making judgements of overall long-term value for money, what is the relative priority that should be given to any effective treatment for early Alzheimer’s disease with evidence of Alzheimer’s disease pathology, on the basis of the following contextual considerations:

3. Magnitude of the lifetime impact on individual patients of the condition being treated

A. Very low priority
B. Low priority
C. Average priority
D. High priority
E. Very high priority
What are the relative effects of lecanemab added to supportive care versus supportive care alone on the following outcomes that inform judgement of the overall long-term value for money of lecanemab added to supportive care?

4. Patients’ ability to achieve major life goals related to education, work, or family life

A. Major negative effect
B. Minor negative effect
C. No difference
D. Minor positive effect
E. Major positive effect
What are the relative effects of lecanemab added to supportive care versus supportive care alone on the following outcomes that inform judgement of the overall long-term value for money of lecanemab added to supportive care?

5. Caregivers’ quality of life and/or ability to achieve major life goals related to education, work, or family life

A. Major negative effect
B. Minor negative effect
C. No difference
D. Minor positive effect
E. Major positive effect

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What are the relative effects of lecanemab added to supportive care versus supportive care alone on the following outcomes that inform judgement of the overall long-term value for money of lecanemab added to supportive care?

6. Society’s goal of reducing health inequities

A. Major negative effect
B. Minor negative effect
C. No difference
D. Minor positive effect
E. Major positive effect
Long-Term Value for Money
7. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with lecanemab added to supportive care versus supportive care alone?

A. Low long-term value for money at current price

B. Intermediate long-term value for money at current price

C. High long-term value for money at current price
Break

Meeting will resume at 1 pm PT
Policy Roundtable
<table>
<thead>
<tr>
<th>Participant</th>
<th>Affiliation</th>
<th>Conflict of Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Victor Henderson, MD, MS</strong>&lt;br&gt;Professor of Neurology</td>
<td>Stanford University</td>
<td>No conflicts to disclose.</td>
</tr>
<tr>
<td><strong>Jason Karlawish, MD</strong>&lt;br&gt;Professor of Medicine</td>
<td>University of Pennsylvania</td>
<td>Dr. Karlawish has received manufacturer support of research in the clinical area of this meeting. Dr. Karlawish has served as a site investigator for clinical trails sponsored by Eli Lilly &amp; Co. and Biogen Inc.</td>
</tr>
<tr>
<td><strong>Doreen Monks, RN, MSN</strong>&lt;br&gt;Patient Advocate</td>
<td>Patient Advocate</td>
<td>No conflicts to disclose.</td>
</tr>
<tr>
<td><strong>Russ Paulsen, MA</strong>&lt;br&gt;Chief Operating Officer</td>
<td>UsAgainstAlzheimer’s</td>
<td>UsAgainstAlzheimer’s receives funding from companies, including less than 25% from Eisai.</td>
</tr>
<tr>
<td><strong>Gail Ryan, PharmD</strong>&lt;br&gt;Director of Pharmaceutical Transformation</td>
<td>Point32Health</td>
<td>Dr. Ryan is a full-time employee of Point32Health.</td>
</tr>
<tr>
<td><strong>Amir A. Tahami, MD, MSc, Ph.D.</strong>&lt;br&gt;Global Value &amp; Access Head, Alzheimer's Disease and Brain Health</td>
<td>Eisai Co., Ltd.</td>
<td>Dr. Tahami is a full-time employee of Eisai Co., Ltd.</td>
</tr>
<tr>
<td><strong>Susan Wojcicki, PharmD, BCOP</strong>&lt;br&gt;Interim Director, Humana Pharmacy Solutions Clinical Drug Evaluation &amp; Policy Strategies</td>
<td>Humana</td>
<td>Dr. Wojcicki is a full-time employee of Humana.</td>
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</table>
CTAF Council Reflections
Next Steps

• Meeting recording posted to ICER website next week

• Final Report published on or around April 17, 2023
  • Includes description of CTAF votes, deliberation, policy roundtable discussion

• Materials available at: https://icer.org/assessment/alzheimers-disease-2022/
Adjourn