Maintenance of Efficacy and Safety With Lebrikizumab up to One Year of Treatment in Patients With Moderate-to-Severe Atopic Dermatitis With or Without Topical Corticosteroids

Emma Guttman-Yassky,1 Stephan Weidinger,2 Jonathan I. Silverberg,3 Melinda Gooderham,4 Jacob P. Thyssen,5 Alan Irvine,6 Hany Elmaraghy,7 Chitra R. Natalie,7 Chaoran Hu,7 Evangeline Pierce,7 Esther Garcia Gil,8 Eric Simpson9

1Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, USA; 2Department of Dermatology and Allergy, University Hospital Schleswig-Holstein, Kiel, Germany; 3Department of Dermatology, George Washington University School of Medicine and Health Sciences, Washington, DC, USA; 4SKIN Centre for Dermatology, Peterborough, Canada; 5Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark; 6Department of Clinical Medicine, Trinity College, Dublin, Ireland; 7Eli Lilly and Company, Indianapolis, USA; 8Almirall, S.A., Barcelona, Spain; 9Oregon Health & Science University, Portland, USA

E. Guttman-Yassky is a consultant for: AbbVie, Almirall, Amgen, Asana BioSciences, Boehring Ingelheim, Cara Therapeutics, Celgene, Concert Pharmaceuticals, DBV Technologies, Dermira, DS Biopharma, Eli Lilly and Company, EMD Serono, Escaler Biosciences, Galderma, Genmark Pharmaceuticals, Kyowa Kirin, LEO Pharma, Mitsubishi Tanabe, Pfizer, RAPT Therapeutics, Regeneron, Sanofi, Sienna Biopharmaceuticals, and UNION Therapeutics; and reports institute grants for research from: AbbVie, Almirall, Amgen, AnaptysBio, Asana BioSciences, Boehringer Ingelheim, Celgene, Dermavant, DS Biopharma, Eli Lilly and Company, Galderma, Genmark Pharmaceuticals, Innovadmir Research, Janssen, Kiniska Pharmaceuticals, Kyowa Kirin, LEO Pharma, Novartis, Pfizer, Ralexr Therapeutics, Regeneron, Sienna Biopharmaceuticals, UCB Pharma, and UNION Therapeutics. S. Weidinger is a speaker, advisory board member, and/or investigator for: AbbVie, Almirall, Eli Lilly and Company, Galderma, Kymab, LEO Pharma, Pfizer, Regeneron, and Sanofi; and has received research grants from: LEO Pharma, Pfizer, and Sanofi; J. I. Silverberg has received grants and/or personal fees from: AbbVie, AFYX Therapeutics, Almirall, Arena Pharmaceuticals, Asana BioSciences, Bluefin Biomedicine, Boehringer Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte Corporation, Kiniska Pharmaceuticals, LEO Pharma, Luna Pharma, Menlo Therapeutics, Novartis, Pfizer, RAPT Therapeutics, Regeneron, and Sanofi; M. Gooderham has been an investigator, speaker, consultant, or advisory board member for: AbbVie, Akros Pharma, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte Corporation, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB Pharma, and Valeant Pharmaceuticals/Bausch Health. J. P. Thyssen is an employee of LEO Pharma, is an advisor for: AbbVie, Almirall, Arena Pharmaceuticals, ASLAN Pharmaceuticals, Bausch Health, Coloplast, Eli Lilly and Company, LEO Pharma, OR Pharma, Pfizer, Regeneron, Sanofi Genzyme, and UNION Therapeutics; and is a speaker for: AbbVie, Almirall, Eli Lilly and Company, LEO Pharma, Pfizer, Regeneron, and Sanofi Genzyme; and has received research grants from: LEO Pharma, OR Pharma, Pfizer, Regeneron, Sanofi Genzyme, and UNION Therapeutics; A. Irvine is a speaker, advisory board member, and/or investigator for: AbbVie, Almirall, Arena Pharmaceuticals, ASLAN Pharmaceuticals, Coloplast, Eli Lilly and Company, LEO Pharma, OR Pharma, Pfizer, Regeneron, Sanofi Genzyme, and UNION Therapeutics; H. Elmaraghy, C. R. Natalie, C. Hu, and E. Pierce are employees and stockholders of: Eli Lilly and Company; E. Garcia Gil is an employee of: Almirall; E. Simpson reports personal fees from: AbbVie, Amgen, Arena Pharmaceuticals, ASLAN Pharmaceuticals, Boston Consulting Group, Collective Acumen (CA), Dermira, Eli Lilly and Company, Evidera, Excerpta Medica, Farbice Biotics, Galderma, GlaxoSmithKline, Incyte Corporation, Janssen, Kyowa Kirin, LEO Pharma, Medscape, Merck, Pfizer, Physicians World, Regeneron, Roivant Sciences, Sanofi Genzyme, Trevi Therapeutics, Valeant Pharmaceuticals, and WebMD (these potential conflicts of interest have been reviewed and managed by OHSU); and reports grants from or serves in a Principal Investigator role for: AbbVie, Amgen, Arcutis, ASLAN Pharmaceuticals, CorEvitas, Dermavant, Dermira, Eli Lilly and Company, Incyte Corporation, Kymab, Kyowa Hakko Kirin, LEO Pharma, Pfizer, Regeneron, Sanofi, and TARGET RWE (these potential conflicts of interest have been reviewed and managed by OHSU).

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This study was funded by Dermira, a wholly owned subsidiary of Eli Lilly and Company. Almirall, S.A. has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including atopic dermatitis, in Europe. Lilly has exclusive rights for development and commercialization of lebrikizumab in the United States and the rest of the world outside of Europe.
Background

- Lebrikizumab is a novel monoclonal antibody that binds with high affinity and slow off-rate to IL-13, thereby blocking the downstream effects of IL-13 with high potency.\(^1\)
- Lebrikizumab was effective in providing clinically meaningful improvements in the signs and symptoms of AD at Week 16 in adult and adolescent patients with moderate-to-severe AD.\(^2,3\)
- ADvocate1 (NCT04146363), ADvocate2 (NCT04178967), ADhere (NCT04250337), and ADjoin (NCT04392154) were 4 Phase 3 trials\(^a\)
  - ADvocate1&2 (total of 52 weeks): Induction (16 weeks) and maintenance treatment (36 weeks) with lebrikizumab in monotherapy
  - ADhere (total of 16 weeks): Induction treatment with lebrikizumab in combination with TCS
  - ADjoin: Long-term treatment with lebrikizumab
  - Patients completing ADhere could roll over into ADjoin

Objective

- To evaluate the maintenance of efficacy and safety of lebrikizumab Q2W and Q4W in lebrikizumab responders\(^b\)
  - In ADvocate1&2 from Weeks 16 to 52
  - In ADjoin from Weeks 0 to 40 (patients rolling over from ADhere)

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\(^a\) ADvocate1&2 and ADhere were randomized, double-blind, placebo-controlled trials; ADjoin may be randomized or non-randomized and patients may either be blinded or not blinded, depending on their parent study assignment;  
\(^b\) Lebrikizumab-treated responders were defined as having an IGA response of 0 or 1 or reporting EASI 75 at the end of the Induction Period


AD=atopic dermatitis; EASI=75% improvement from baseline in Eczema Area and Severity Index; IGA=Investigator’s Global Assessment; IL=interleukin; Q2W=every 2 weeks; Q4W=every 4 weeks; TCS=topical corticosteroids
Study Design

**Study Design**

**ADvocate1&2**

<table>
<thead>
<tr>
<th>Induction</th>
<th>Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD&lt;sup&gt;a&lt;/sup&gt;</td>
<td>LEB 250 mg Q2W</td>
</tr>
<tr>
<td>R 2:2:1</td>
<td>LEB 250 mg Q2W</td>
</tr>
<tr>
<td>Resp&lt;sup&gt;c&lt;/sup&gt;</td>
<td>LEB 250 mg Q4W</td>
</tr>
<tr>
<td>Non-Resp</td>
<td>LEB withdrawal Q2W&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>LEB 250 mg Q2W</td>
<td>LEB 250 mg Q2W</td>
</tr>
</tbody>
</table>

**Use of TCS prohibited**

- Intermittent use of TCS permitted<sup>b</sup>

<table>
<thead>
<tr>
<th>TCS use, n (%)</th>
<th>LEB Withdrawal</th>
<th>LEB Q4W</th>
<th>LEB Q2W</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8 (13.3)</td>
<td>14 (11.9)</td>
<td>11 (9.7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weeks</th>
<th>0</th>
<th>16</th>
<th>52</th>
</tr>
</thead>
<tbody>
<tr>
<td>R 2:1</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**ADhere**

**ADhere: Induction**

- LD<sup>a</sup>
- LEB 250 mg Q2W + TCS
- R 2:1
- Resp<sup>c</sup>
- Non-Resp
- LEB 250 mg Q2W + TCS

<table>
<thead>
<tr>
<th>Weeks</th>
<th>0</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>R 2:1</td>
<td></td>
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</tr>
</tbody>
</table>

**ADjoin**

**ADjoin: Long-Term Extension**

- LD<sup>a</sup>
- LEB 250 mg Q2W + TCS
- R 2:1
- Resp<sup>c</sup>
- Non-Resp
- LEB 250 mg Q2W + TCS

<table>
<thead>
<tr>
<th>Weeks</th>
<th>0</th>
<th>16</th>
</tr>
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<tbody>
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**TCS use, n (%)**

<table>
<thead>
<tr>
<th></th>
<th>LEB Q4W</th>
<th>LEB Q2W</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>23 (79.3)</td>
<td>40 (70.2)</td>
</tr>
</tbody>
</table>

**Notes:**
- LEBe-treated patients received a 500-mg LD at Weeks 0 and 2. Responders who received PBO and were re-randomized to LEB received an LD of LEB 500 mg at Week 16 or at Weeks 18 and 18, based on the active treatment group assigned in the Maintenance Period. Responders were defined as having an IGA response of 0 or 1 or reporting EASI 75 at the end of the Induction Period without use of rescue therapy. LEB withdrawal. Patients who may require short-term systemic treatment for AD in the Maintenance Period are assessed on a case-by-case basis. TCS treatment will be initiated at baseline in all patients and may be tapered or stopped, as needed, based on treatment response; the study drug was discontinued for patients receiving systemic rescue treatment. Patients who may require long-term systemic treatment for symptoms of AD are discontinued from the study. AD=atopic dermatitis; EASI=75% improvement from baseline in Eczema Area and Severity Index; IGA=Investigator’s Global Assessment; LD=loading dose; LEBe=brilizumab; Non-resp=non-responders; PBO=placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; R=randomization; Resp=responders; TCS=topical corticosteroids
### Methods

#### Key Eligibility Criteria

- Adults (≥18 years) and adolescents (≥12 to <18 years; weighing ≥40 kg)
- Diagnosis of AD, as defined by the American Academy of Dermatology Consensus Criteria, for ≥1 year before screening
- Moderate-to-severe AD, defined as having all the following at the baseline visit:
  - EASI ≥16
  - IGA ≥3
  - BSA involvement ≥10%

#### Analysis Population

- Lebrikizumab Week 16 responders in ADvocate1 (ITT population) and ADvocate2 (mITT population, Weeks 16-52)
- Lebrikizumab responders from ADhere rolling over to ADjoin (mITT population, Weeks 0-40)

#### Safety analyses:
- Randomized patients who received ≥1 dose of study drug

#### Statistical Analyses

- NRI was used to handle missing data due to lack of efficacy (ADvocate1, ADvocate2, and ADjoin) or data after systemic rescue medication use (in ADvocate1&2, intermittent TCS use was allowed; in ADjoin, TCS use was allowed)
- MI was used for other missing data
- CIs were calculated using asymptotic method without continuity correction

### Outcomes

From Weeks 16 to 52 (ADvocate1&2) or to Week 56 (ADjoin):

- Maintenance of response for:
  - IGA (0,1)
  - EASI 75
- EASI 90 response rates among EASI 75 responders

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* Some study participants did not meet the eligibility criteria of having moderate-to-severe AD. In ADvocate2 and ADhere, 18 and 17 patients, respectively, were excluded from the ITT population; Lebrikizumab-treated responders were defined as having an IGA response of 0 or 1 or reporting EASI 75 at the end of the Induction Period without having a Pruritus NRS ≥4-point improvement at the end of the Induction Period and having a baseline Pruritus NRS ≥4; Safety analyses for the Induction Period were conducted on all randomized patients who received ≥1 dose of study drug in ADvocate1; in ADvocate2, except for the 18 excluded patients; and in ADhere, except for the 17 excluded patients.

AD=atopic dermatitis; BSA=body surface area; CI=confidence interval; EASI=Eczema Area and Severity Index; EASI 75/90=Eczema Area and Severity Index improvement from baseline in EASI; IGA=Investigator’s Global Assessment; ITT=Intent-to-Treat; MI=multiple imputation; mITT=modified ITT; NRI=non-responder imputation; NRS=Numeric Rating Scale; TCS=topical corticosteroids
## Results

**Baseline Demographics and Disease Characteristics in Lebrikizumab Responders\(^a\) at Week 16**

<table>
<thead>
<tr>
<th></th>
<th>ADvocate1&amp;2(^b)</th>
<th>ADhere → ADjoin(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LEB Withdrawal (N=60)</td>
<td>LEB Q4W (N=118)</td>
</tr>
<tr>
<td>Age, years</td>
<td>33.8 (16.6)</td>
<td>35.8 (17.3)</td>
</tr>
<tr>
<td>Adolescent (≥12 to &lt;18 years), n (%)</td>
<td>8 (13.3)</td>
<td>17 (14.4)</td>
</tr>
<tr>
<td>Adult (≥18 years), n (%)</td>
<td>52 (86.7)</td>
<td>101 (85.6)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>36 (60.0)</td>
<td>69 (58.5)</td>
</tr>
<tr>
<td>Region, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>22 (36.7)</td>
<td>51 (43.2)</td>
</tr>
<tr>
<td>Europe</td>
<td>18 (30.0)</td>
<td>38 (32.2)</td>
</tr>
<tr>
<td>Rest of the world</td>
<td>20 (33.3)</td>
<td>29 (24.6)</td>
</tr>
<tr>
<td>BMI, kg/m(^2)</td>
<td>25.3 (4.8)</td>
<td>26.2 (5.9)</td>
</tr>
<tr>
<td>Disease duration since AD onset, years</td>
<td>20.4 (14.9)</td>
<td>22.6 (14.8)</td>
</tr>
<tr>
<td>IGA, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 (Moderate)</td>
<td>37 (61.7)</td>
<td>78 (66.1)</td>
</tr>
<tr>
<td>4 (Severe)</td>
<td>23 (38.3)</td>
<td>40 (33.9)</td>
</tr>
<tr>
<td>EASI</td>
<td>28.9 (11.2)</td>
<td>28.8 (12.6)</td>
</tr>
<tr>
<td>Pruritus NRS</td>
<td>7.5 (1.8)</td>
<td>7.0 (2.1)</td>
</tr>
<tr>
<td>&lt;4, n (%)</td>
<td>2 (3.4)</td>
<td>9 (7.8)</td>
</tr>
<tr>
<td>≥4, n (%)</td>
<td>57 (96.6)</td>
<td>107 (92.2)</td>
</tr>
</tbody>
</table>

\(^a\) LEB-treated responders were defined as having an IGA response of 0 or 1 or reporting EASI 75 at the end of the Induction Period without use of rescue therapy; \(^b\) Pooled modified maintenance primary population for ADvocate1&2; \(^c\) Patients coming from the parent study (ADhere) who were LEB Q2W responders were randomized in ADjoin

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AD=atopic dermatitis; BMI=body mass index; EASI=Eczema Area and Severity Index; EASI 75=75% improvement from baseline in EASI; IGA=Investigator’s Global Assessment; LEB=lebrikizumab; NRS=Numeric Rating Scale; Q2W=every 2 weeks; Q4W=every 4 weeks; SD=standard deviation

Note: Data are mean (SD) unless stated otherwise.

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AD=atopic dermatitis; BMI=body mass index; EASI=Eczema Area and Severity Index; EASI 75=75% improvement from baseline in EASI; IGA=Investigator’s Global Assessment; LEB=lebrikizumab; NRS=Numeric Rating Scale; Q2W=every 2 weeks; Q4W=every 4 weeks; SD=standard deviation
Results

IGA (0,1) Response Rates Were Maintained in Responders Receiving Lebrikizumab Q2W/Q4W, Regardless of TCS Use During the Induction Period

- Responders were defined as having an IGA response of 0 or 1 at the end of the Induction Period

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\[\text{ADvocate1&2}^a\]

\[\text{ADjoin}^b\]
Results

EASI 75 Response Rates Were Maintained in Responders Receiving Lebrikizumab Q2W/Q4W, Regardless of TCS Use During the Induction Period

- Responders were defined as reporting EASI 75 at the end of the Induction Period

EASI 75 Response Rates Were Maintained in Responders Receiving Lebrikizumab Q2W/Q4W, Regardless of TCS Use During the Induction Period

EASI 75-75% improvement from baseline in Eczema Area and Severity Index; LEB=lebrikizumab; PBO=placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; TCS=topical corticosteroids

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* Intermittent TCS use was permitted in the Maintenance Period; a total of 11.3% of patients used TCS (PBO: 13.3%; LEB Q4W: 11.9%; LEB Q2W: 9.7%). † Patients continued or stopped TCS use, as needed; a total of 73.3% of patients used TCS (LEB Q4W: 79.3%; LEB Q2W: 70.2%)
EASI 90 Response at Week 16 Was Maintained or Increased Over Time

- EASI 90 response rates from Weeks 16 to 52 (ADvocate1&2) or to Week 56 (ADjoin) among EASI 75 responders

**Results**

- EASI 90 response rates from Weeks 16 to 52 (ADvocate1&2) or to Week 56 (ADjoin) among EASI 75 responders

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**ADvocate1&2**

- **Weeks on Treatment**
- **EASI 90 Response Rate (%)**

**ADjoin**

- **Weeks on Treatment**
- **EASI 90 Response Rate (%)**

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*Responders were defined as reporting EASI 75 or having an IGA response of 0 or 1 at the end of the Induction Period; intermittent TCS use was permitted in the Maintenance Period; a total of 11.3% of patients used TCS (PBO: 13.3%; LEB Q4W: 11.9%; LEB Q2W: 9.7%); Patients continued or stopped TCS use, as needed; a total of 73.3% of patients used TCS (LEB Q4W: 79.3%; LEB Q2W: 70.2%)

EASI 75/90=75%/90% improvement from baseline in Eczema Area and Severity Index; IGA=Investigator’s Global Assessment; LEB=lebrikizumab; PBO=placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; TCS=topical corticosteroids
Results

Pruritus NRS Response Rates Were Maintained in Responders Receiving Lebrikizumab Q2W/Q4W, Regardless of TCS Use During the Induction Period

- Responders were defined as having Pruritus NRS ≥4-point improvement at the end of the Induction Period and having a baseline Pruritus NRS ≥4

* Intermittent TCS use was permitted in the Maintenance Period; a total of 11.3% of patients used TCS (PBO: 13.3%; LEB Q4W: 11.9%; LEB Q2W: 9.7%); * Patients continued or stopped TCS use, as needed; a total of 73.3% of patients used TCS (LEB Q4W: 79.3%; LEB Q2W: 70.2%)

LEB=lebrikizumab; NRS=Numeric Rating Scale; PBO=placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; TCS=topical corticosteroids

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* ADvocate1&2a

- Pruritus NRS ≥4-point improvement Response Rate (%)

- Weeks on Treatment

  - LEB withdrawal (N=28)
  - LEB Q4W (N=65)
  - LEB Q2W (N=61)

* ADjoinb

- Pruritus NRS ≥4-point improvement Response Rate (%)

- Weeks on Treatment

  - LEB Q4W + TCS (N=16)
  - LEB Q2W + TCS (N=30)
# Results

## Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>ADvocate1&amp;2&lt;sup&gt;a&lt;/sup&gt;</th>
<th>ADhere → ADjoin&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LEB Withdrawal (N=60)</td>
<td>LEB Q4W (N=118)</td>
</tr>
<tr>
<td>Patients with ≥1 TEAE</td>
<td>30 (50.0)</td>
<td>61 (51.7)</td>
</tr>
<tr>
<td>Mild</td>
<td>15 (25.0)</td>
<td>24 (20.3)</td>
</tr>
<tr>
<td>Moderate</td>
<td>15 (25.0)</td>
<td>31 (26.3)</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>6 (5.1)</td>
</tr>
<tr>
<td>Serious AE</td>
<td>1 (1.7)</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Discontinuation from study treatment due to an AE&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Conjunctivitis cluster&lt;sup&gt;d&lt;/sup&gt;</td>
<td>5 (8.3)</td>
<td>12 (10.2)</td>
</tr>
<tr>
<td>Injection site reactions&lt;sup&gt;e&lt;/sup&gt;</td>
<td>0</td>
<td>1 (0.8)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Pooled modified maintenance primary population for ADvocate1&2; <sup>b</sup> Patients coming from the parent study (ADhere) who were LEB Q2W responders and were randomized in ADjoin; <sup>c</sup> Including death; <sup>d</sup> Conjunctivitis cluster is defined using specific MedDRA preferred terms conjunctivitis, conjunctivitis allergic, conjunctivitis bacterial, conjunctivitis viral, and giant papillary conjunctivitis; <sup>e</sup> Injection site reactions are defined using MedDRA high level term of injection site reactions, excluding joint-related preferred terms; <sup>f</sup> As reported by the Investigator, a 56-year-old male died of natural causes on Study Day 462 and the event was assessed to be unrelated to study treatment; the patient had a medical history of hypertension, cardiac ablation, AD, insomnia, and gastroesophageal reflux.

Note: Data are n (%)

AD=atopic dermatitis; AE=adverse event; LEB=lebrikizumab; MedDRA=Medical Dictionary for Regulatory Activities; Q2W=every 2 weeks; Q4W=every 4 weeks; TEAE=treatment-emergent AE
Conclusions

- Patients who responded to lebrikizumab treatment during the Induction Period demonstrated a durable response in the signs and symptoms of moderate-to-severe AD, regardless of concomitant TCS use during the Induction Period:
  - Through to Week 52 in ADvocate1&2
  - Through to Week 40 in ADhere → ADjoin
- Adverse events were mostly non-serious, mild or moderate in severity, and did not lead to treatment discontinuation
- Safety profile of lebrikizumab in patients with moderate-to-severe AD was generally consistent with previously published data
- Treatment response rates with lebrikizumab Q4W was similar to the one with Q2W

* Intermittent TCS use was permitted in the Maintenance Period
AD=atopic dermatitis; Q2W=every 2 weeks; Q4W=every 4 weeks; TCS=topical corticosteroids