# Lebrikizumab P2b Topline Results

March 18, 2019

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# Executive Summary

- Clinical profile has the potential to significantly alter the treatment landscape in AD
- Selective inhibition of IL-13 with lebrikizumab could be the best approach to treating AD
- All three doses of lebrikizumab met primary endpoint with statistical significance
- Robust dose-dependent efficacy across multiple measures
- Well-tolerated with safety profile consistent with prior studies
- Results warrant rapid advancement to Phase 3 program; planned by end of 2019 after End-of-Phase 2 meeting with FDA

# Lebrikizumab: Compelling Investment Thesis

- Biologic atopic dermatitis therapy is a large and growing market
  - Predicted to be as large as approximately $14.8 billion by 2025[1]
  - Need for new, differentiated therapies

- Lebrikizumab offers a differentiated mechanism of action that has the potential to be a best-in-disease therapy for treating AD
  - IL-13/IL-4 class is a validated, targeted approach

- Phase 2b study confirms thesis that lebrikizumab may potentially offer a compelling combination of efficacy, safety, tolerability, convenience and ease-of-use

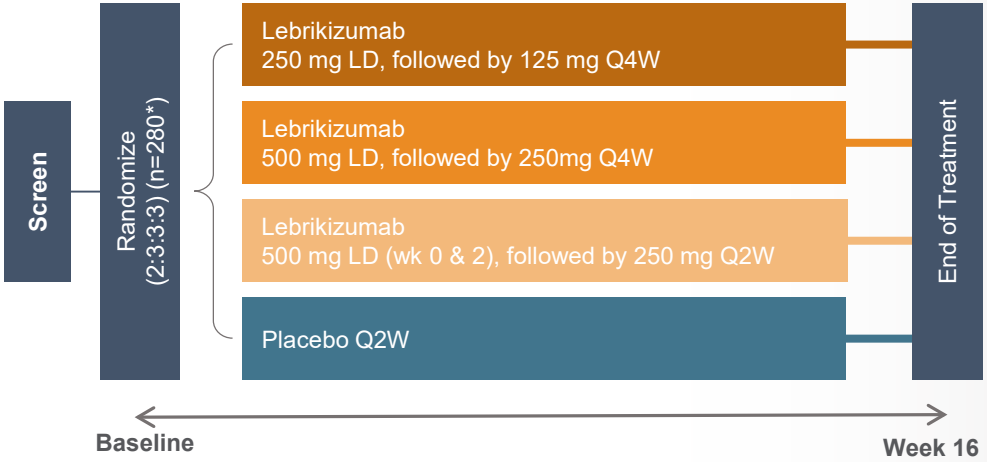


- Phase 2b topline results announced on March 18, 2019
- Planned Phase 3 initiation by end of 2019, after End-of-Phase 2 meeting; expect topline data first half 2021[2]

1. Decision Resources (2017); 2. Estimate provided as of March 18, 2019. Expected topline results timing assumes Phase 3 initiation by year-end 2019

# Phase 2b Study to Optimize Product Profile

**Study Design:**




## Study objectives

- Optimize dosing regimen to enhance product profile
- Define monotherapy profile

## Key inclusion criteria

- Adults with moderate-to-severe AD not adequately controlled with topicals or for whom topical treatment is medically inadvisable
- TCS washout prior to randomization

## Key endpoints (response rates at week 16)

- Primary endpoint
  - Percent change in EASI
- Secondary endpoints include:
  - ≥ 2-point reduction from baseline and a final IGA score of 0/1
  - EASI-50, EASI-75, EASI-90
  - Pruritus NRS

Abbreviations: Q2W (every 2 weeks), Q4W (every 4 weeks), TCS (topical corticosteroids), IGA (Investigator Global Assessment), EASI (Eczema Area and Severity Index), NRS (numerical rating scale). Over the 16-week period, approximately 56% in the placebo arm discontinued compared to approximately 22% across the lebrikizumab dosing arms.

# Study Protocol

## Inclusion criteria

- Chronic AD has been present for ≥1 year before screening visit
- EASI score ≥16 at screening and baseline visits
- IGA score of 3 or 4 (scale of 0 to 4) at screening and baseline visits
- ≥10% body surface area (BSA) of AD involvement at screening and baseline visits

## Statistical analysis considerations

- Statistical tests were two sided and performed at the 0.05 level of significance
- The primary method of handling missing efficacy data was the Markov Chain Monte Carlo (MCMC) multiple imputation

## Rescue treatment

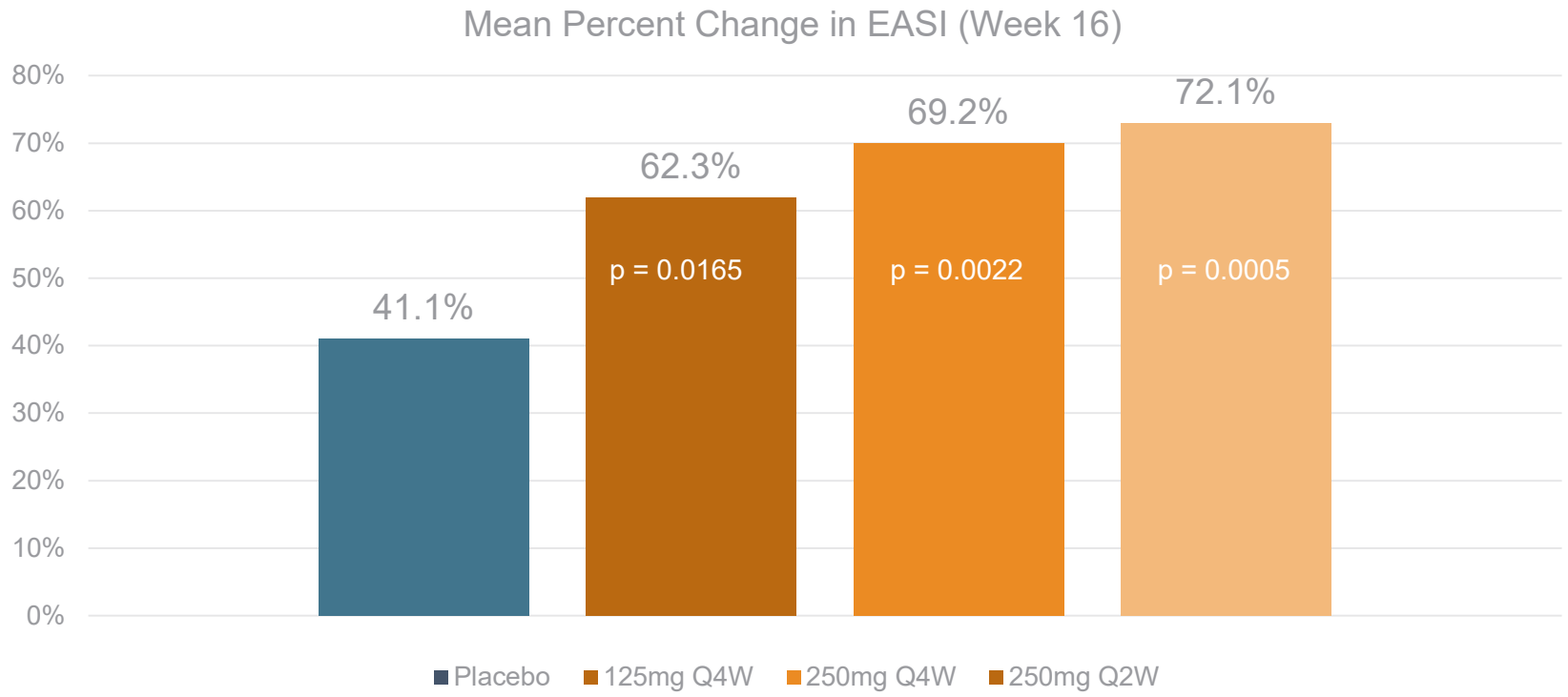
- Patients were permitted rescue therapy, including topical corticosteroids, in all arms recommended by the investigator
- If patients used systemic therapy, they had to discontinue the treatment
- A total of approximately 13% and 35% received rescue therapy in the treatment and placebo arms, respectively

# Select Baseline Disease Characteristics

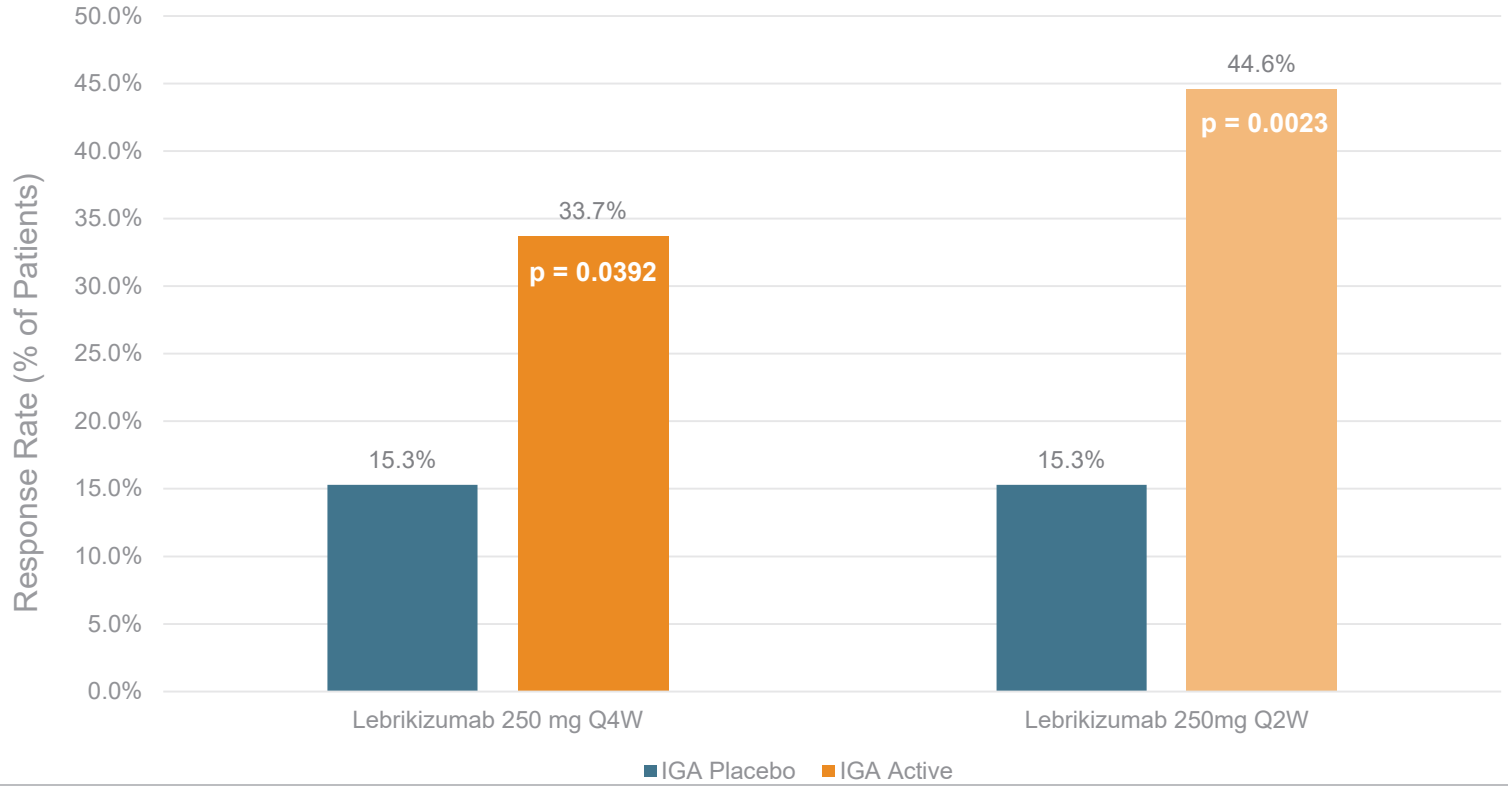
| | | 125 mg Q4W (n=73) | 250 mg Q4W (n=80) | 250 mg Q2W (n=75) | Placebo (n=52) |
|---|---|---|---|---|---|
| EASI Score | n | 73 | 80 | 75 | 52 |
| | Mean | 29.852 | 26.146 | 25.477 | 28.903 |
| | SD | 13.5174 | 10.1346 | 11.2057 | 11.7900 |
| IGA (%) | n | 73 | 80 | 75 | 52 |
| | 3 - Moderate | 43 (58.9%) | 54 (67.5%) | 53 (70.7%) | 32 (61.5%) |
| | 4 - Severe | 30 (41.1%) | 26 (32.5%) | 22 (29.3%) | 20 (38.5%) |
| BSA | n | 73 | 80 | 75 | 52 |
| | Mean | 45.5 | 41.1 | 39.4 | 46.5 |
| | SD | 24.49 | 20.89 | 21.49 | 22.68 |
| Pruritus Score | n | 68 | 77 | 69 | 49 |
| | Mean | 7.6 | 7.1 | 7.6 | 7.4 |
| | SD | 1.98 | 2.44 | 1.87 | 2.42 |
| DLQI Score | n | 72 | 80 | 75 | 52 |
| | Mean | 14.5 | 14.2 | 14.1 | 14.1 |
| | SD | 7.10 | 7.66 | 6.94 | 7.07 |

Dermira data on file

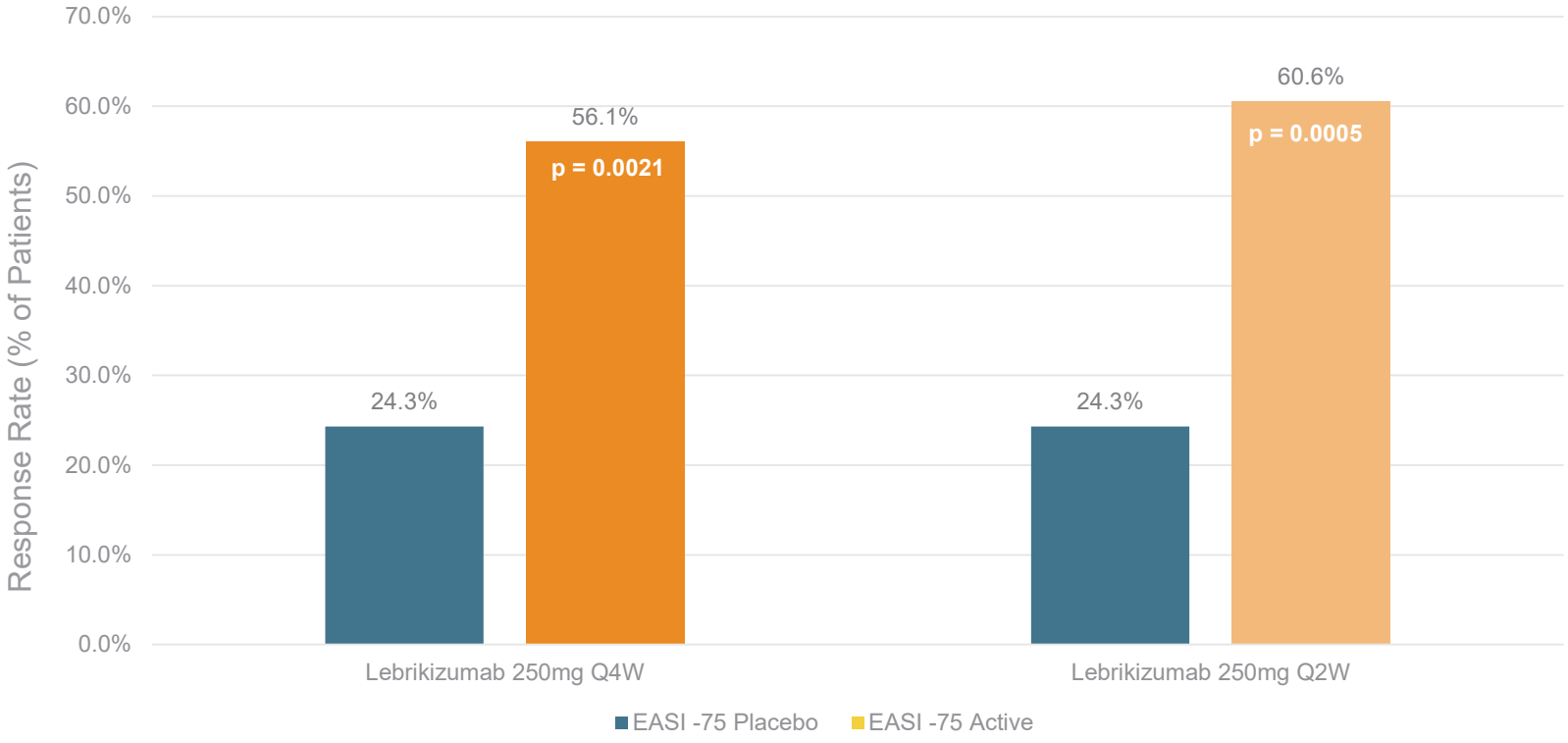
# Primary Endpoint: EASI Improvement



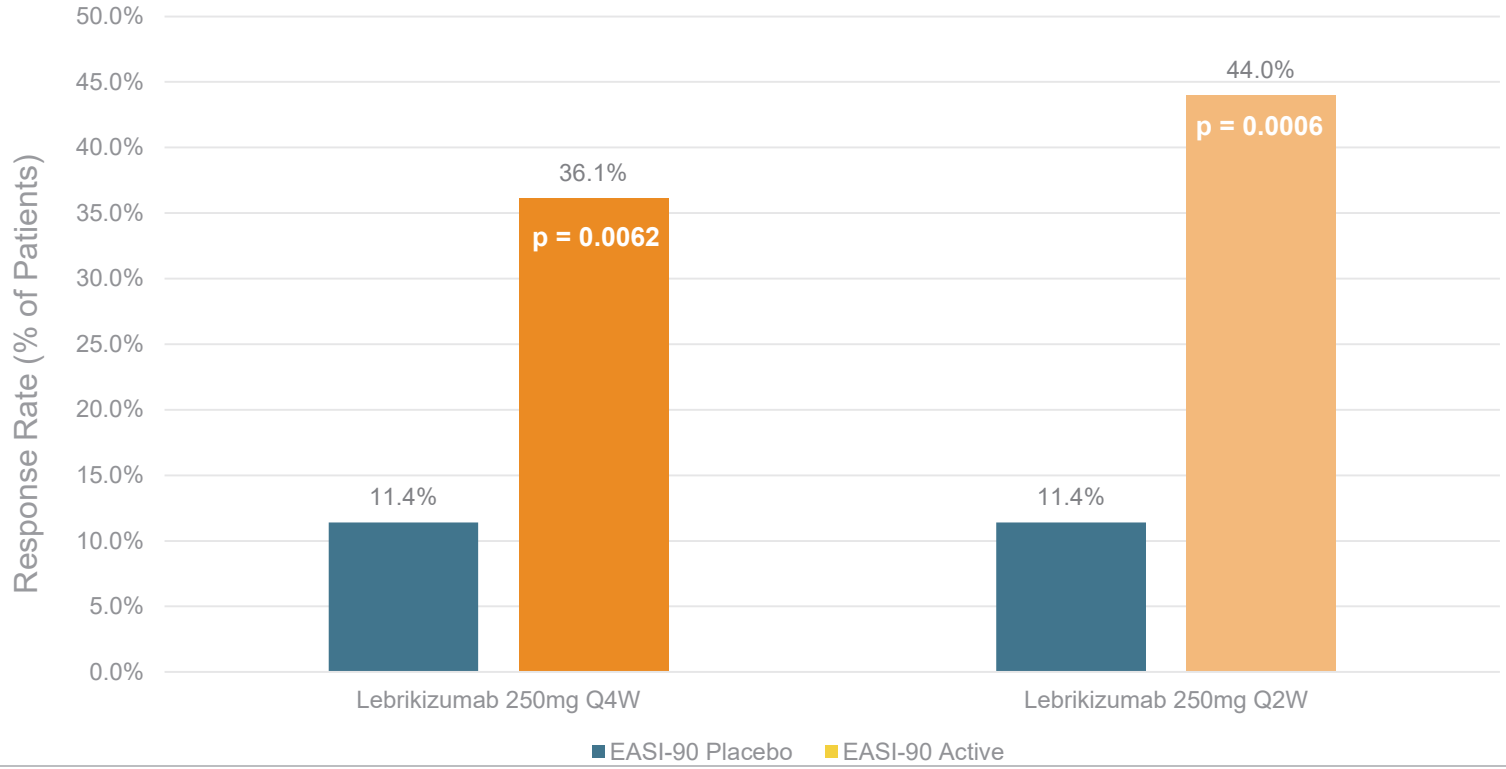
# Efficacy: Investigators Global Assessment



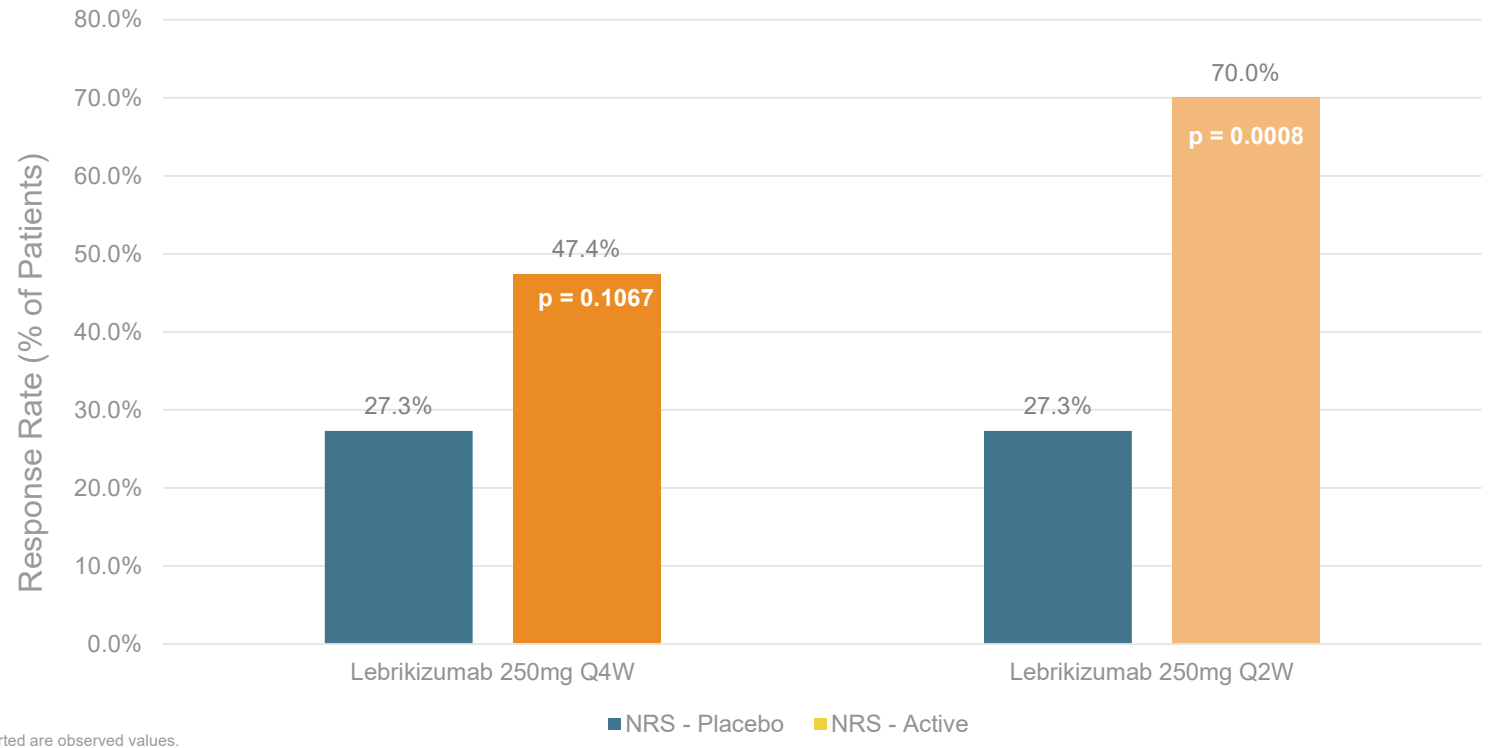
# Efficacy: EASI-75



# Efficacy: EASI-90



# Pruritus: NRS, ≥4 Point Improvement




All data reported are observed values.

# Adverse Events: Lebri Was Well Tolerated

| Most Frequent Adverse Events | Placebo (n=52) | 125mg Lebri Q4W (n=73) | 250mg Lebri Q4W (n=80) | 250mg Lebri Q2W (n=75) | All Lebri (n=228) |
|---|---|---|---|---|---|
| Upper Respiratory Tract Infection | 3 (5.8%) | 6 (8.2%) | 9 (11.3%) | 2 (2.7%) | 17 (7.5%) |
| Nasopharyngitis | 2 (3.8%) | 4 (5.5%) | 2 (2.5%) | 9 (12.0%) | 15 (6.6%) |
| Fatigue | 0 | 0 | 4 (5.0%) | 0 | 4 (1.8%) |
| Headache | 3 (5.8%) | 2 (2.7%) | 1 (1.3%) | 4 (5.3%) | 7 (3.1%) |
| Injection Site Pain | 1 (1.9%) | 0 | 3 (3.8%) | 4 (5.3%) | 7 (3.1%) |
| Herpes Zoster | 0 | 0 | 1 (1.3%) | 1 (1.3%) | 2 (0.9%) |
| Herpes Infections | 0 | 2 (2.7%) | 2 (2.5%) | 1 (1.3%) | 5 (2.2%) |
| Conjunctivitis | 0 | 1 (1.4%) | 3 (3.8%) | 2 (2.7%) | 6 (2.6%) |

Dermira data on file

# Dupilumab Profile Can Be Improved Upon

| | Endpoints | Dupilumab – SOLO 1[1] | Dupilumab – SOLO 2[1] | Dupilumab – P2b[2] |
|---|---|---|---|---|
| **Efficacy** | IGA: Score of 0 to 1, "Clear" or "Almost Clear" | 38% vs. 10% | 36% vs. 8% | 30% vs. 2% |
| | Improvement in EASI Score | 72% vs. 38% | 67% vs. 31% | 71% vs. 20% |
| | EASI-50 | 69% vs. 25% | 65% vs. 22% | 78% vs. 30% |
| | EASI-75 | 51% vs. 15% | 44% vs. 12% | 53% vs. 12% |
| | EASI-90 | 36% vs 8% | 30% vs. 7% | 30% vs. 3% |
| | Pruritus Improvement (NRS): ≥ 4 point Improvement | 41% vs. 12% | 36% vs. 10% | NR |
| | % change in Peak Weekly Averaged Pruritus NRS | 51% vs. 27% | 47% vs. 18% | 46% vs. 0.4% |
| **Safety and Tolerability** | Serious AE %<br><br>AEs > 1% Incidence | Serious AEs: 3% vs. 5%<br>Injection Site Reaction: 10% vs. 5%<br>Conjunctivitis: 10% vs. 2%<br>Oral Herpes: 4% vs. 2%<br>Oral Herpes simplex virus infection: 2% vs. 1% | Data reported under SOLO 1 is combined safety from SOLO 1 and SOLO2 | Serious AEs: 2% vs. 7%<br>Injection Site Reaction: NR<br>Conjunctivitis: 5% vs. 3%<br>Oral Herpes: 5% vs. 0%<br>Oral Herpes simplex virus infection: 3% vs. 0% |
| **Dosing** | Dosing Frequency and Loading | loading dose of 2 injections (600mg) followed by a maintenance dose of 1 injection (300mg) given **every two weeks (Q2W)** | loading dose of 2 injections (600mg) followed by a maintenance dose of 1 injection (300mg) given **every two weeks (Q2W)** | loading dose of 2 injections (600mg) followed by a maintenance dose of 1 injection (300mg) given **every two weeks (Q2W)** |

1. NEJM 2016;375:2335-48, 2. Lancet 2016; 387; 40-52

# Conclusions

- These data suggest that taking a selective approach to addressing IL-13 inhibition with lebrikizumab may be the best approach to treating AD
- Based on the compelling efficacy results observed, lebrikizumab may have the potential to be a truly differentiated therapy and may offer a best-in-disease treatment option for patients living with AD
- These data suggest that lebrikizumab may also be differentiated on its safety, tolerability and dosing profile
- Plan to have End-of-Phase 2 meeting with FDA and initiate Phase 3 program by end of 2019

# Thank You

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