**Dermatitis Symptoms and Quality of Life from BREEZE-AD4 and BREEZE-AD7 Phase 3 Trials**

**Study Design, BREEZE-AD7**

**METHODS**

- **Key Inclusion Criteria**
  - ≥18 years old and diagnosis of AD for ≥12 months
  - Key Inclusion Criteria
    - Moderate-to-severe AD at screening and randomization, defined as:
      - EASI ≥16 or vIGA-AD (0,1) = vIGA-AD (clear or almost clear)
  - Patients completing W104 who had a contraindication to cyclosporine (BREEZE-AD4) or were intolerant to, or had a contraindication to topical corticosteroids (TCS) in adults with:
  - Moderate-to-severe AD who had an inadequate response to topical therapies (BREEZE-AD7)
  - Moderate-to-severe AD who had an inadequate response to topical therapies and either experienced failure, were intolerant to, or had a contraindication to cyclosporine (BREEZE-AD4)

- **Objective**
  - To examine patient-reported measures of AD symptoms and quality of life (QoL) using data from BREEZE-AD7 and BREEZE-AD4

- **Key Results**
  - Proportion of Patients with DLQI 24-Poitn Improvement*
  - Proportion of Patients with DLQI (0,1)*
  - Change from Baseline in PGI-S-AD

- **Conclusions**
  - Daily treatment with baricitinib, plus TCS vs. placebo plus TCS achieved rapid improvement in QoL starting as early as Week 1 in adult patients with moderate-to-severe AD (BREEZE-AD4 and BREEZE-AD7)
  - Patients in BREEZE-AD4 had history of inadequate response, contraindication, or intolerance to cyclosporine
  - Clinically significant QoL improvements were maintained through Week 16
  - Improvements in QoL are also reflected in significant improvements achieved in patient-reported reduction in disease severity seen as early as Week 1 and sustained through Week 16

- **Methods**
  - Study Design, BREEZE-AD7
  - Study Design, BREEZE-AD4

- **Assessments and Analyses**
  - Baseline Demographics and Disease Characteristics

- **References**
  - Fridman JS, et al.
  - Basra MK, et al.
  - Reich K, et al.

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*FE Yang, M Tauber, C Paul, E Moelants (Non-Author Presenter)*

**BACKGROUND**

- Baricitinib is an oral, selective Janus kinase (JAK)1/JAK2 inhibitor in development for the treatment of moderate-to-severe atopic dermatitis (AD)
- BREEZE-AD7 (NCT03733301) and BREEZE-AD4 (NCT03428100) are multicenter, randomized, double-blind, placebo-controlled, Phase 3 studies evaluating the efficacy and safety of baricitinib in combination with topical corticosteroids (TCS) in adults with:
  - Moderate-to-severe AD who had an inadequate response to topical therapies (BREEZE-AD7)
  - Moderate-to-severe AD who had an inadequate response to topical therapies and either experienced failure, were intolerant to, or had a contraindication to cyclosporine (BREEZE-AD4)

**RESULTS**

- Baseline Demographics and Disease Characteristics

**Abbreviations**

- AD: Atopic dermatitis
- AAD: Atopic dermatitis and eczema
- BREEZE: Baricitinib Research Evaluation and Evaluation of Eczema
- BDD: Belgian Dermatology Days
- BDI: Beck Depression Inventory
- CGSD: Clinical Global Severity Discomfort
- DLQI: Dermatology Life Quality Index
- EASI: Eczema Area and Severity Index
- ITT: Intent-to-Treat
- JAK: Janus kinase
- KM: Kaplan-Meier
- MMRM: Mixed-effects model of repeated-measures
- PBO: Placebo
- PGI-S: Patient Global Impression of Severity
- PRO: Patient-reported outcome
- QoL: Quality of Life
- RCT: Randomized controlled trial
- vIGA: Validated Investigator Global Assessment
- W: Week

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**Disclosure**

- All authors contributed to the study design, data analysis, and writing of the manuscript. No potential conflicts of interest were reported.

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