Temporal Response Patterns of Long-Term Abrocitinib Treatment in JADE EXTEND Following Dupilumab Treatment in JADE COMPARE and JADE DARE

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- **BG** has worked as a consultant for Pfizer Inc. and Genentech; as a speaker/consultant for CSL Behring, Horizon Therapeutics, Regeneron, and Sanofi-Genzyme; and is on advisory boards for Novartis and Shire
- **PB**, **EG,** and **MW** are employees and shareholders of Pfizer Inc.

Background and Objectives

Background

- AD is a chronic inflammatory disease that may require long-term treatment with systemic agents to control disease signs and symptoms[1,2]
- Abrocitinib, an oral JAK1-selective inhibitor, and dupilumab, an injectable IL-4Rα antagonist, demonstrated efficacy in patients with moderate-to-severe AD in the phase 3 JADE COMPARE and JADE DARE trials[3,4]
- In clinical practice, patients may need to switch from dupilumab to abrocitinib treatment due to intolerance, inadequate efficacy, lack of access, or preference for oral versus injectable delivery[5]

Objectives

- To assess the long-term efficacy of abrocitinib in patients whose symptoms did not respond to dupilumab in JADE COMPARE and JADE DARE
- To contextualize these findings with efficacy data from patients who received abrocitinib throughout JADE COMPARE, JADE DARE, and the ongoing long-term extension study, JADE EXTEND

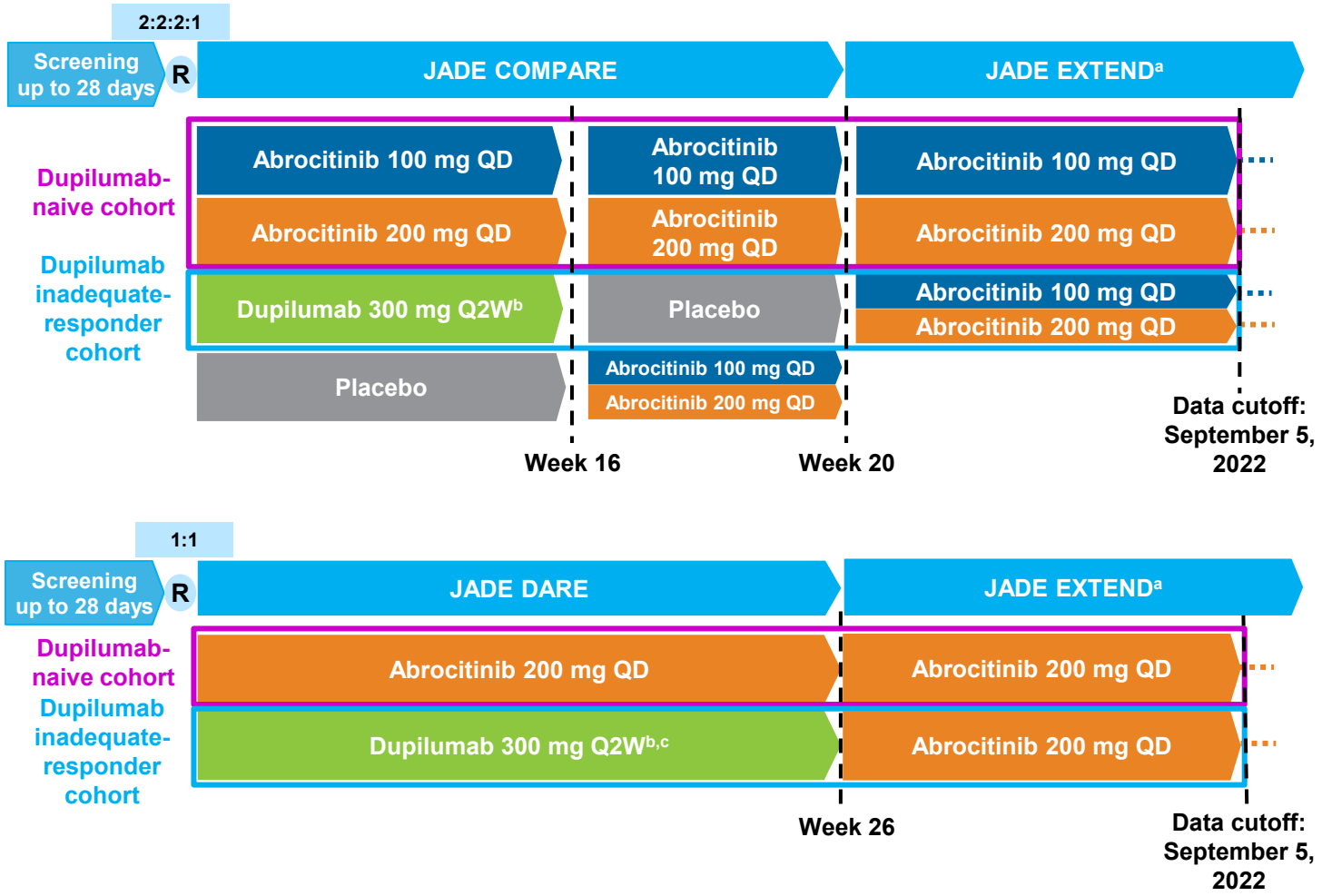
AD, atopic dermatitis; IL-4Rα, interleukin 4 receptor alpha; JAK1, Janus kinase 1.
ClinicalTrials.gov Identifiers: NCT04345367 (JADE DARE); NCT03720470 (JADE COMPARE); NCT03422822 (JADE EXTEND).
1. Davis DMR et al. *J Am Acad Dermatol*. 2024;90(2):e43-e56. 2. Reich K et al. *J Eur Acad Dermatol Venereol*. 2023;37(10):2056-2066. 3. Bieber T et al. *N Eng J Med*. 2021:384;12. 4. Reich K et al. *Lancet*. 2022;400(10348):273-282. 5. Shi VY et al. *J Am Acad Dermatol*. 2022;87(2):351-358.

Study Design and Patients

Study Design and Patients

- This post hoc analysis included adult patients who received abrocitinib or dupilumab with medicated topical therapy in JADE COMPARE (16 weeks)[1] or DARE (26 weeks)[2] and enrolled in the ongoing abrocitinib long-term extension study, JADE EXTEND
- Patients were further categorized based on previous dupilumab treatment history
  - Dupilumab-naive cohort: patients who received abrocitinib in JADE COMPARE and DARE and continued to receive abrocitinib in EXTEND
  - Dupilumab inadequate-responder cohort: patients who did not achieve adequate response after treatment with dupilumab in JADE COMPARE and DARE and were treated with abrocitinib in EXTEND
- Concomitant medicated topical therapies were permitted throughout the studies

Study Design



Q2W, once every 2 weeks; QD, once daily.
ClinicalTrials.gov Identifiers: NCT04345367 (JADE DARE); NCT03720470 (JADE COMPARE); NCT03422822 (JADE EXTEND).
[a]As of the data cutoff. JADE EXTEND is an ongoing study. [b]After a loading dose of 600 mg. [c]Patients in JADE DARE had their final dupilumab dose at Week 24.
1. Bieber T et al. *N Eng J Med*. 2021:384;12. 2. Reich K et al. *Lancet*. 2022;400(10348):273-282.

Assessments and Statistical Analyses

Assessments

- The proportion of patients in the dupilumab-naive and dupilumab inadequate-responder cohorts who achieved EASI-90, PP-NRS 0/1, EASI-90 + PP-NRS 0/1, and DLQI-4 were assessed to Week 60 of JADE EXTEND

Statistical Analyses

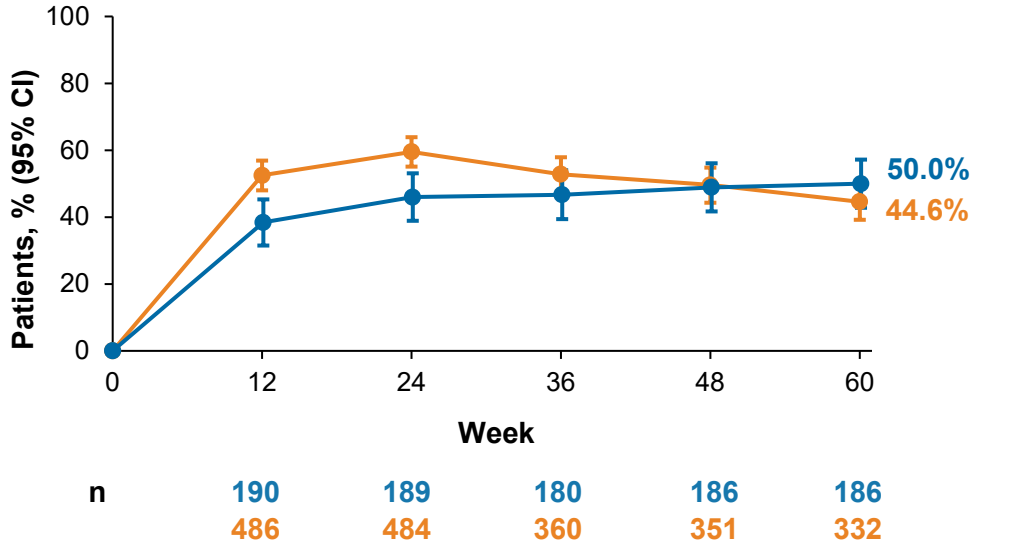
- Efficacy was assessed in the full analysis set, defined as all randomly assigned patients who received at least 1 dose of abrocitinib
- Baseline was defined as the measurement collected on or prior to Day 1
- Patients who withdrew from the study or used rescue therapy were counted as nonresponders after that point
- The estimate and CIs for differences were calculated based on weighted average of difference by disease severity group using the normal approximation of binomial proportions
  - CIs for response rates were based on normal approximation (or the Clopper-Pearson exact method, when there were 0 or 100% responders)
- Post hoc analyses have limited sample size and are not powered for testing any hypotheses

DLQI-4, ≥4-point improvement from baseline in Dermatology Life Quality Index; EASI-90; ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0/1.
ClinicalTrials.gov Identifiers: NCT04345367 (JADE DARE); NCT03720470 (JADE COMPARE); NCT03422822 (JADE EXTEND).

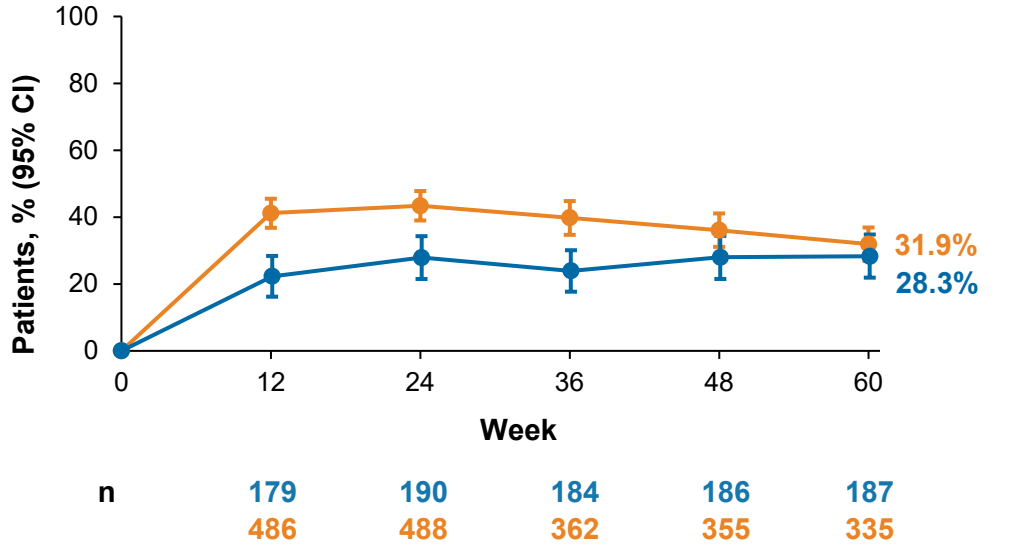
Efficacy Responses With Abrocitinib in the Dupilumab-Naive Cohort During JADE EXTEND

- Greater proportions of the dupilumab-naive cohort achieved the stringent endpoints of EASI-90 and PP-NRS 0/1 at earlier time points with abrocitinib 200 mg compared with abrocitinib 100 mg
- Response rates were higher with abrocitinib 200 mg versus abrocitinib 100 mg as early as Week 2 of treatment; however, long-term efficacy responses were similar between the treatment arms

EASI-90



PP-NRS 0/1



Abrocitinib 100 mg

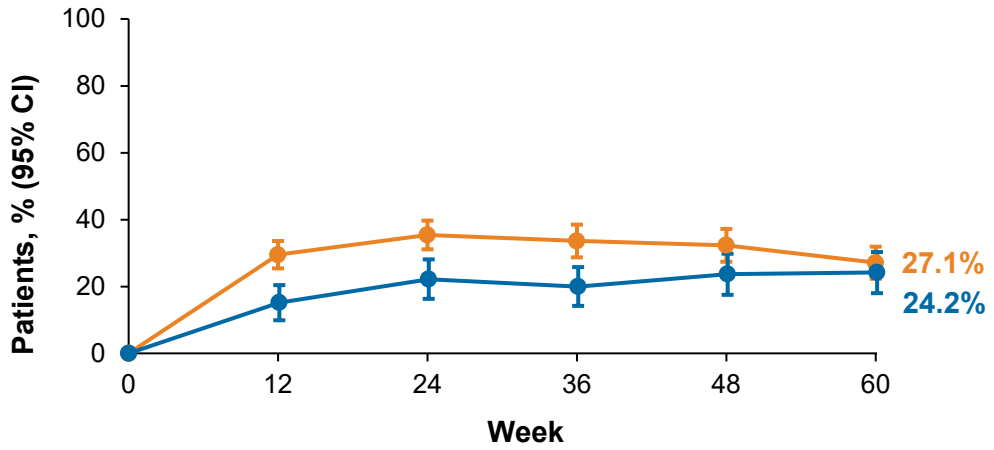
Abrocitinib 200 mg

EASI-90; ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0 (no itch) or 1 (very little itch).
Time points refer to total exposure on abrocitinib, combining across parent studies (COMPARE and DARE) and going on to EXTEND.

Efficacy Responses With Abrocitinib in the Dupilumab-Naive Cohort During JADE EXTEND

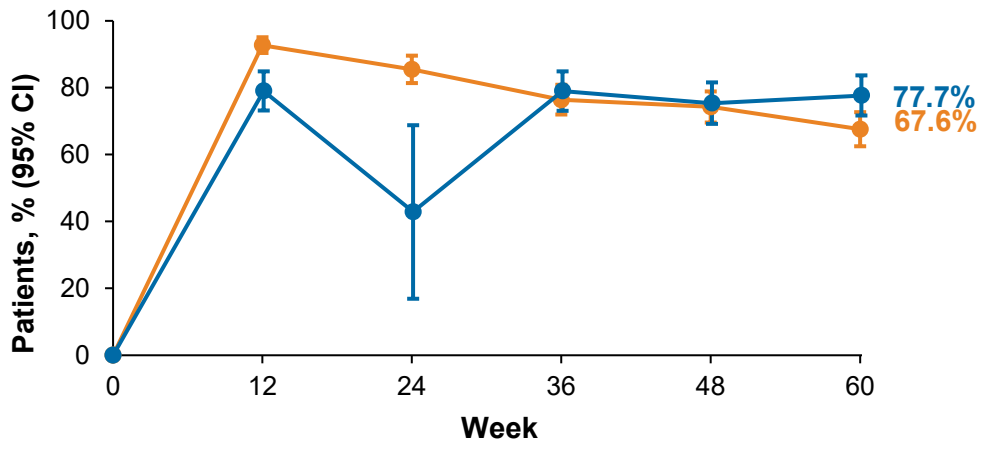
- Similarly, greater proportions of the dupilumab-naive cohort achieved the stringent endpoints of EASI-90 + PP-NRS 0/1 and DLQI-4 at early time points with abrocitinib 200 mg compared with abrocitinib 100 mg
- Response rates were higher with abrocitinib 200 mg versus 100 mg as early as Week 2 of treatment, although comparative proportions of patients achieved these endpoints at Week 60 with abrocitinib at either dose

EASI-90 + PP-NRS 0/1



n					
Abrocitinib 100 mg	178	189	180	186	186
Abrocitinib 200 mg	481	483	360	350	332

DLQI-4



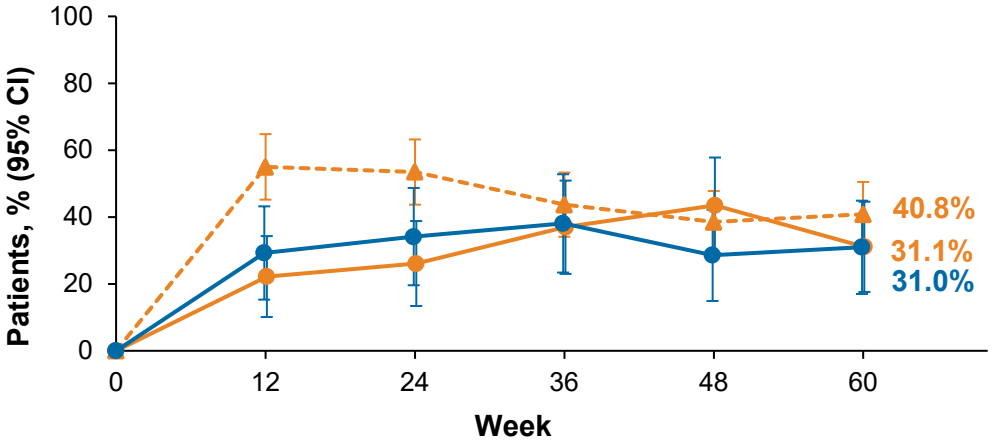
n					
Abrocitinib 100 mg	186	14	181	183	184
Abrocitinib 200 mg	467	283	348	342	324

DLQI-4, ≥4-point improvement from baseline in Dermatology Life Quality Index; EASI-90; ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0 (no itch) or 1 (very little itch).
Time points refer to total exposure on abrocitinib, combining across parent studies (COMPARE and DARE) and going on to EXTEND.

Efficacy Responses With Abrocitinib in the Dupilumab Inadequate-Responder Cohort During JADE EXTEND

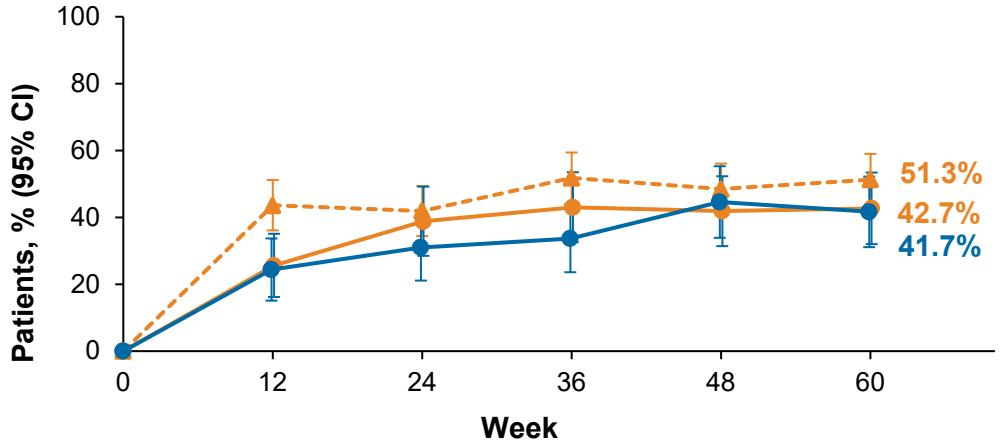
- Substantial proportions of the dupilumab inadequate-responder cohort from JADE DARE and COMPARE achieved the stringent endpoints of EASI-90 and PP-NRS 0/1 at Week 12 of abrocitinib treatment in EXTEND
- Improvements were largely maintained up to Week 60

EASI-90



JADE DARE, n	100	101	103	104	98
JADE COMPARE, n	41	41	42	42	42
	45	46	46	46	45

PP-NRS 0/1



JADE DARE, n	165	167	166	167	160
JADE COMPARE, n	82	84	83	83	84
	82	85	86	86	82

JADE DARE
Abrocitinib 200 mg

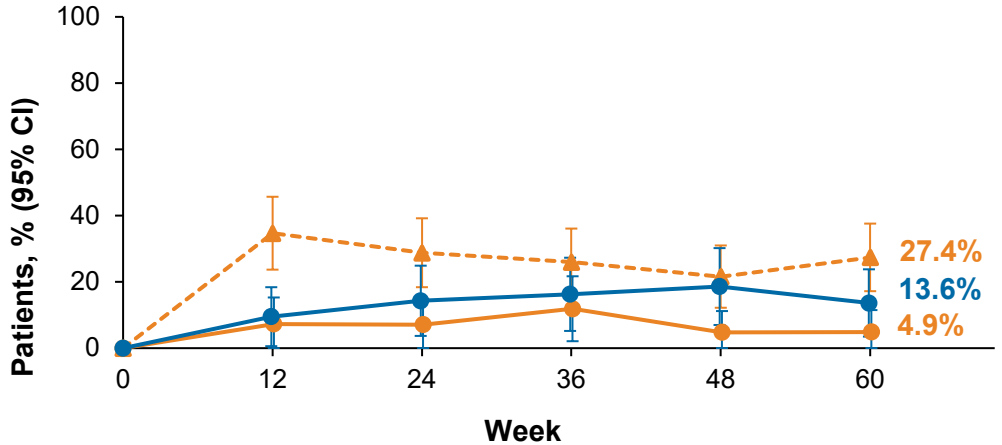
JADE COMPARE
Abrocitinib 100 mg
Abrocitinib 200 mg

EASI-90; ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0/1.
Time points refer to respective visits in JADE EXTEND.

Efficacy Responses With Abrocitinib in the Dupilumab Inadequate-Responder Cohort During JADE EXTEND

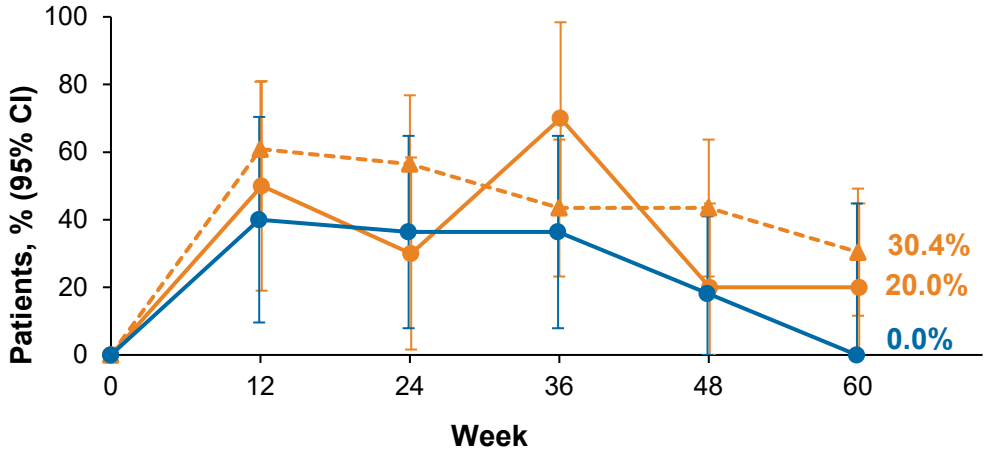
- Similarly, substantial proportions of the dupilumab inadequate-responder cohort achieved the stringent endpoints of EASI-90 + PP-NRS 0/1 and DLQI-4 at Week 12 of abrocitinib 200 treatment
- The EASI-90 + PP-NRS 0/1 combined response rate was maintained through Week 60 in the long-term extension study, while DLQI-4 response rates were more variable due to low patient numbers

EASI-90 + PP-NRS 0/1



JADE DARE, n	72	73	73	74	73
JADE COMPARE, n	42	42	43	43	44
	41	42	42	42	41

DLQI-4



JADE DARE, n	23	23	23	23	23
JADE COMPARE, n	10	11	11	11	10
	10	10	10	10	10

JADE DARE
Abrocitinib 200 mg

JADE COMPARE
Abrocitinib 100 mg
Abrocitinib 200 mg

DLQI-4, ≥4-point improvement from baseline in Dermatology Life Quality Index; EASI-90; ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0/1.
Time points refer to respective visits in JADE EXTEND.

Conclusions

- Long-term efficacy was observed with abrocitinib 200 mg and 100 mg up to Week 60
- For many patients with previous inadequate response to dupilumab treatment, abrocitinib may be an effective treatment option