Economic Impact of Abrocitinib Monotherapy and Combination Therapy in Patients With Moderate-to-Severe Atopic Dermatitis: Results From JADE MONO-2 and JADE COMPARE

Melinda J. Gooderham,[1] Chia-Yu Chu,[2] Ricardo Rojo,[3] Hernan Valdez,[4] Pinaki Biswas,[4] Michael C. Cameron,[4] Claire Feeney,[5] Gerardo A. Encinas,[6] Kathleen Peeples-Lamirande,[7] Joseph C. Cappelleri,[3] Daniela E. Myers,[7] Marco DiBonaventura[4]

[1]*SKiN Centre for Dermatology, Peterborough, ON, Canada;* [2]*Department of Dermatology, National Taiwan University Hospital and National Taiwan University College of Medicine, Taipei, Taiwan;* [3]*Pfizer Inc., Groton, CT, USA;* [4]*Pfizer Inc., New York, NY, USA;* [5]*Pfizer Ltd., Surrey, United Kingdom;* [6]*Pfizer Inc., Vancouver, BC, Canada;* [7]*Pfizer Inc., Collegeville, PA, USA*

BACKGROUND

- Atopic dermatitis (AD) is a common, chronic, relapsing-remitting inflammatory skin condition, characterized by intense itch, lesions, and dry skin[1]
- Given the high and increasing prevalence of AD,[1] the potential financial burden on patients and society through direct and indirect costs is substantial[2-4]
  - Direct costs include hospitalization and outpatient visits, prescription costs, and over-the counter pharmacy costs; indirect costs primarily include lost wages because of absenteeism or presenteeism as a result of AD signs and symptoms
- Abrocitinib, an oral once-daily selective Janus kinase 1 inhibitor, was effective and well tolerated in 2 phase 3 monotherapy studies (JADE MONO-1, NCT03349060; JADE MONO-2, NCT03575871) and a phase 3 combination therapy study (JADE COMPARE, NCT03720470)[5-7]
  - However, the potential economic impact of abrocitinib in patients with moderate-to-severe AD remains unknown

OBJECTIVE

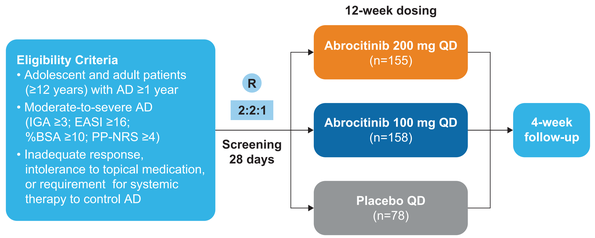
- To assess the indirect and direct economic impact of abrocitinib (200 mg and 100 mg) monotherapy and combination therapy in patients with moderate-to-severe AD using data from JADE MONO-2 and JADE COMPARE

METHODS

Study Overview

- JADE MONO-2 was a multicenter, randomized, double-blind, placebo-controlled, monotherapy study[6] (**Figure 1**)

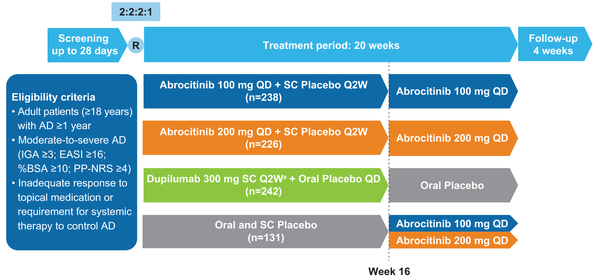
Figure 1. Study Design



%BSA, percentage of affected body surface area; AD, atopic dermatitis; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale (used with permission of Regeneron Pharmaceuticals, Inc., and Sanofi); QD once daily; R, randomization.

- JADE COMPARE was a multicenter, randomized, double-blind, double-dummy, placebo-controlled, combination study[7] (**Figure 2**)

Figure 2. JADE COMPARE Study Design



All groups used background medicated topical therapy (low- or medium-potency corticosteroids, calcineurin inhibitors, and phosphodiesterase 4 inhibitors) for active lesions, but not all patients did so

%BSA, percentage of affected body surface area; AD, atopic dermatitis; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; QD, once daily; Q2W, every 2 weeks; R, randomization; SC, subcutaneous.

[a]After 600-mg SC loading dose of dupilumab, as per label.

Economic Outcomes

- Work Productivity and Activity Impairment–AD questionnaire, version 2.0 (WPAI-AD), from JADE MONO-2 included scores for absenteeism (percentage of work time missed), presenteeism (percentage impairment experienced while at work), and overall work impairment (combination of absenteeism and presenteeism) owing to AD
  - Indirect costs due to productivity loss were estimated using the human capital approach
    - The reduction in overall work impairment from baseline to week 12 was multiplied by the annual median wage in the United States from the Bureau of Labor Statistics ($49,348, based on data for the first quarter of 2020)[8]
- Healthcare resource utilization (HCRU) questionnaire from JADE COMPARE included assessment of the number of physician visits in the past 3 months at baseline and week 16
  - Direct costs were calculated by multiplying the reduction in the number of physician visits, based on charges made by physicians, across these 2 time periods by the physician visit unit cost from the Agency for Health Research and Quality ($265, based on the overall mean expense for an office visit in 2016)[9]
- Indirect and direct costs were annualized on a per-patient basis

Statistical Analysis

- Economic outcomes were analyzed in the full analysis set (FAS), defined as all randomly assigned patients who received at least 1 dose of study medication
  - No dupilumab treatment group was included in JADE MONO-2; therefore, dupilumab treatment was not assessed using the WPAI-AD questionnaire
- An analysis of covariance (ANCOVA) model was used, including treatment as a main effect and randomization strata (baseline disease severity and age category) and baseline of outcome variables as covariates

RESULTS

Demographics and Baseline Disease Characteristics

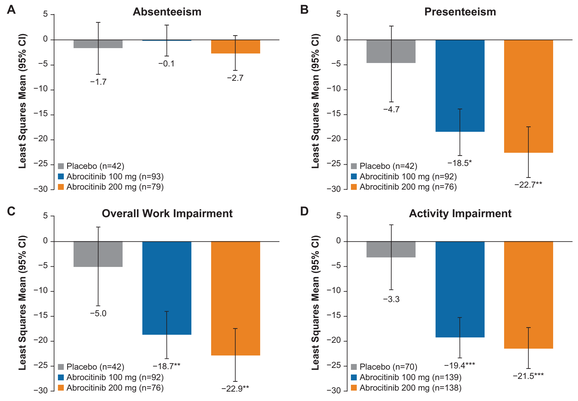
- Demographics and baseline characteristics were similar among patients treated with abrocitinib or placebo from JADE MONO-2 and JADE COMPARE and among patients treated with abrocitinib and dupilumab in COMPARE
- In this post hoc analysis, 1228 (JADE MONO-2: 391, JADE COMPARE: 837) patients were included at baseline, of which 210-347[a] patients from JADE MONO-2 completed the WPAI-AD questionnaire for absenteeism, presenteeism, overall work impairment, and activity impairment (200 mg: 76-138; 100 mg: 92-139; placebo: 42-70) and 720 patients from JADE COMPARE completed the HCRU questionnaire for physician visits (200 mg: 196; 100 mg: 204; dupilumab injection 300 mg [Dupixent; Sanofi and Regeneron Pharmaceuticals, Inc.]: 211, placebo: 109)

[a]Range in n values pertains to varying number of patients who completed each questionnaire (ie, absenteeism, presenteeism, overall work impairment, and activity impairement).

Economic Outcomes

- Patients treated with abrocitinib monotherapy (200 mg or 100 mg) compared with placebo in JADE MONO-2 reported greater improvement in presenteeism, overall work impairment, and activity impairment at week 12 (**Figure 3**)

Figure 3. Least Squares Mean Change From Baseline in WPAI in JADE MONO-2 at Week 12 for (A) Absenteeism, (B) Presenteeism, (C) Overall Work Impairment, and (D) Activity Impairment

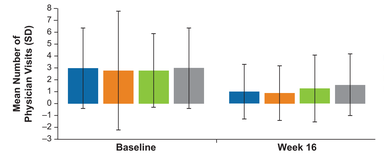


WPAI, Work Productivity and Activity Impairment questionnaire.

*P≤0.05, **P<0.001, ***P<0.0001 for abrocitinb compared with placebo.

- Patients taking abrocitinib (200 mg, 100 mg), dupilumab, or placebo in conjunction with background topical therapy in JADE COMPARE reported a decrease in mean number of physician visits from baseline (**Figure 4**)

Figure 4. Physician Visits in JADE COMPARE at Week 16



[a]Range in n values from baseline to week 16.

Indirect and Direct Costs

- The reduction in indirect annual cost per patient for abrocitinib 200 mg and 100 mg in JADE MONO-2 was estimated to be $11,301 and $9228, respectively, based on median weekly earnings for the first quarter of 2020[8]
- The reduction in direct annual cost per patient for abrocitinib 200 mg and 100 mg in JADE COMPARE was estimated to be $1636 and $1723, respectively, based on the overall mean expense for an office visit in the United States in 2016[9]

CONCLUSION

- Abrocitinib (200 mg and 100 mg) had a positive impact on presenteeism, overall work impairment, and activity impairment compared with placebo in JADE-MONO-2; patients in all treatment groups in JADE COMPARE reported a similar decrease in the total median number of physician visits
  - A limitation of this analysis is that randomized controlled trials represent an artificial environment as it relates to interaction between the patients and the healthcare system; additional real-world assessments might be necessary to confirm these results, particularly the direct cost estimates
- Both the 200-mg and 100-mg doses of abrocitinib monotherapy and combination therapy could reduce indirect and direct costs by improving work-related impairment and reducing the number of outpatient physician visits

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