C-206 Real-World Prospective Data Assessing the Long-Term Safety of Abrocitinib Treatment in Adults with Moderate to Severe Atopic Dermatitis (AD): Over Two Years of Experience from the CorEvitas AD Registry [1225]

Sampada Gandhi,[1] Bernice Gershenson,[2] Heather Chubb,[2] Bryan Cherry,[2] Nathan Rubin,[2] Christine J. Barr,[2] Melissa Moore-Clingenpeel,[2] Dimitrios A. Pappas,[2] Haiyun Fan,[3] Cristina Lumpan,[4] Jen Weissert,[5] Pinaki Biswas,[1] Gary Chan[6]

[1]Pfizer Inc., New York, NY, USA; [2]Thermo Fisher Scientific, Waltham, MA, USA; [3]Pfizer Inc., Collegeville, PA, USA; [4]Pfizer B.V., Capelle aan den IJssel, the Netherlands; [5]Pfizer Inc., Cambridge, MA, USA; [6]Pfizer Inc., Groton, CT, USA

ABSTRACT

Background: Abrocitinib is an oral Janus kinase inhibitor (JAKi) approved in the United States (US) in 2022 for adults with moderate-to-severe atopic dermatitis (AD). A post-approval prospective observational study assessing long-term safety of abrocitinib in AD patients from the US and Canada using the CorEvitas AD Registry from 2022 to 2034 is ongoing.

Objectives: To estimate the incidence rates (IRs) of prespecified delayed (eg, malignancies) and acute-onset (eg, serious infections) safety events separately in AD patients exposed to abrocitinib and in a comparator cohort exposed to biologic and non-biologic (non-JAKi) chronic systemic AD treatments.

Methods: AD patients ≥18 years enrolled in the Registry during 14 Jan 2022 - 3 Jul 2024 who received abrocitinib or a comparator drug within 12 months prior to, at or after Registry enrollment were included in the study. Crude IRs for each safety event [number of first events per 100 patient-years (PY)] and 95% confidence intervals (CI) based on Poisson counts were calculated.

Results: Delayed-onset outcomes: Mean (±SD) age of patients was 47.0 (±18.6) and 51.5 (±18.6) years in the abrocitinib (n=100) and comparator cohort (n=1096), respectively. The abrocitinib cohort was comprised of 51.0% female and 65.0% White compared to 57.1% female and 72.5% White in the comparator cohort. The total follow-up exposure time in the abrocitinib and comparator cohorts was 87.3 and 1168.0 PY, respectively. There were 0 and 17 total malignancies in the abrocitinib and comparator cohorts, with an IR per 100 PY of 0.0 (95% CI: 0.0-4.2) and 1.5 (95% CI: 0.9-2.4), respectively.

Acute-onset outcomes: Mean (±SD) age of patients was 46.6 (±18.3) and 51.4 (±18.4) years in the abrocitinib (n=88 exposures) and comparator cohort (n=996 exposures), respectively. Of the total abrocitinib exposures, 53.4% were female and 61.4% White compared to 58% female and 72.9% White in the comparator exposures. The total follow-up exposure time in the abrocitinib and comparator cohorts was 58.7 and 833.8 PY, respectively. The number of events and IRs per 100 PY (95% CI) in the abrocitinib cohort were as follows: major adverse cardiac events (MACE), retinal detachment (RD), thrombosis and hepatotoxicity [n=0]; opportunistic infection (OI) [n=1, 1.7 (0.0-9.6)]; serious infections (SI) [n=2, 3.4 (0.4-12.4)]. The number of events and IRs per 100 PY (95% CI) in the comparator cohort were as follows: RD and hepatotoxicity [n=0]; MACE and thrombosis [n=2, 0.2 (0.0-0.9)], OI [n=6, 0.7 (0.3-1.6)]; SI [n=11, 1.3 (0.7-2.4)].

Conclusions: During 2 years, no new safety signals and a low incidence of prespecified safety events was observed in the abrocitinib cohort, aligning with the known safety profile of abrocitinib.

DISCLOSURES

SG, **HF**, **CL**, **JW**, **PB**, and **GC** are employees and stockholders of Pfizer Inc. **BG**, **HC**, **CJB**, and **MM-C** are employees and stockholders of Thermo Fisher Scientific, Inc. **DAP** is an employee and stockholder of Thermo Fisher Scientific, Inc; a member of the Board of Directors of the Corrona Research Foundation; and has received honoraria/consulting fees from AbbVie, Genentech, Novartis, Sanofi, and Roche. **BC** and **NR** are employees of Thermo Fisher Scientific, Inc.

BACKGROUND

- Atopic dermatitis (AD) is a chronic inflammatory skin condition with a relapsing-remitting disease course that requires long-term treatment to maintain control of symptoms[1,2]
- Abrocitinib is an oral, once-daily, Janus kinase 1 (JAK1)-selective inhibitor approved for the treatment of adults and adolescents with moderate-to-severe AD in multiple countries, including the United States (US)[3,4]
- A recent integrated safety analysis of abrocitinib in 3802 patients with moderate-to-severe AD from the JADE clinical trial program, including data from more than 5200 patient-years (PY) with up to 4 years of exposure, supported a manageable safety profile with long-term abrocitinib treatment[5]
- Real-world evidence, such as post-approval studies, is crucial to understanding the safety profile of drugs beyond the controlled setting of clinical trials[6,7]

OBJECTIVE

- To estimate the crude incidence rates (IRs) of prespecified delayed- and acute-onset safety events in patients with AD exposed to abrocitinib and in a comparator cohort of patients with AD exposed to biologic or nonbiologic (non–JAK inhibitor) chronic systemic therapies for AD

METHODS

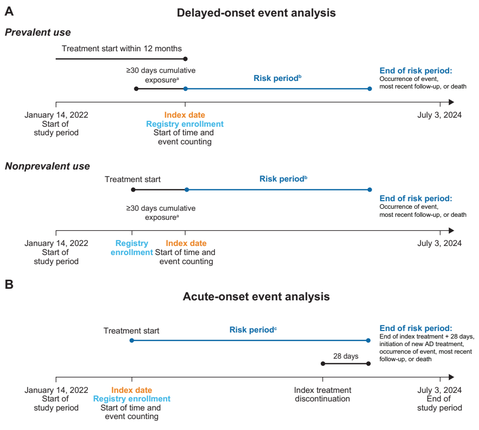
Study Design and Data Source

- A prospective, observational, post-approval safety study of abrocitinib in patients with AD from the US and Canada using the PPD CorEvitas AD Registry from 2022 to 2034 is ongoing
  - The PPD CorEvitas AD Registry is a prospective, multicenter, disease-based Registry that enrolls patients through a network of dermatology practices in the US and Canada[8]
- This analysis used data collected between January 14, 2022 (approval date of abrocitinib for adults with moderate-to-severe atopic dermatitis in the US), and July 3, 2024

Participants and Setting

- Data were included from adult patients (aged ≥18 years) enrolled in the PPD CorEvitas AD Registry with a diagnosis of AD from a dermatologist or qualified provider who initiated abrocitinib or a defined systemic comparator therapy within the 12 months prior to, at, or after Registry enrollment
  - Treatment initiation was defined as first-ever use of the medication
  - Systemic comparators included any biologic (dupilumab, tralokinumab-ldrm, and lebrikizumab) or nonbiologic (azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, systemic corticosteroids [prednisone, kenalog, and methylprednisolone], triamcinolone injection, and other parenteral corticosteroids [eg, dexamethasone]) therapy approved for the treatment of AD prior to or during the study period
- This study separately analyzed delayed-onset safety events of interest and acute-onset safety events of interest (**Figure 1**)
- For inclusion in the delayed-onset event analysis, patients may have initiated eligible treatment within 12 months prior to Registry enrollment, at, or after Registry enrollment; initiations that occurred more than 12 months prior to enrollment were not included
  - The index date was defined as the date after 30 days of cumulative use of a qualifying treatment (not necessarily consecutive)
  - For the prevalent treatment population (patients who initiated the qualifying treatment within 12 months prior to Registry enrollment, with ≥30 days of cumulative treatment use prior to Registry enrollment), the index date was the date of Registry enrollment
  - For the nonprevalent treatment population (patients who initiated the qualifying treatment at or after Registry enrollment), the index date was the day after 30 days of cumulative (not necessarily consecutive) treatment
- For inclusion in the crude report for the acute-onset analysis, patients must have started treatment at or after Registry enrollment; patients may have had prior exposure to abrocitinib or systemic comparator (ie, ≥1 dose of abrocitinib or systemic comparator therapy was allowed)
  - The index date was defined as the date of abrocitinib or comparator treatment start

Figure 1. Study Design for the **A**) Delayed-Onset Event Analysis and **B**) Acute-Onset Event Analysis



[a]Cumulative (not necessarily consecutive) use of a qualifying treatment.

[b]The risk period began the day after ≥30 days of cumulative treatment exposure or Registry enrollment, whichever occurred later.

[c]Patients who underwent treatment switch (ie, patients who discontinued abrocitinib or systemic comparator treatment before switching to systemic comparator or abrocitinib treatment, respectively) contributed to the risk period of the new treatment group at the start of the new treatment.

Main Outcome Measures

- Safety was assessed by monitoring for prespecified safety events of interest (**Table 1**)

Table 1. Prespecified Safety Events of Interest

Delayed-Onset Outcomes	Acute-Onset Outcomes
• Total malignancies • Malignancies (excluding NMSC) • NMSC	• Serious infections • Opportunistic infections • MACE (including MI, stroke, and cardiovascular death) • Retinal detachment • Herpes zoster • Thrombosis (including DVT, PE, and arterial thrombosis) • Hepatotoxicity (including drug-induced liver injury)

DVT, deep vein thrombosis; MACE, major adverse cardiovascular event; MI, myocardial infarction; NMSC, nonmelanoma skin cancer; PE, pulmonary embolism.

Statistical Analyses

- Crude IRs for each prespecified safety event of interest were provided with 95% confidence intervals (CIs), calculated based on the assumption that the actual count of cases was derived from a Poisson distribution
  - IRs are presented as number of events per 100 PY; only the first event per patient within the exposure period was used in the calculation

RESULTS

Patients and Exposures

Delayed-Onset Outcomes Analysis

- A total of 1196 patients were included in the delayed-onset outcomes analysis, including 100 patients treated with abrocitinib (total exposure: 87.3 PY) and 1096 patients treated with a systemic comparator therapy (1168.0 PY)
- Patient demographics and baseline disease characteristics are shown in **Tables 2** and **3**
  - Most patients were female and White across treatment cohorts

Table 2. Demographics for Patients Included in the Delayed-Onset Outcomes Analysis

	Abrocitinib N=100	Systemic Comparator Therapy N=1096
Age at index, years		
Mean (SD)	47.0 (18.6)	51.5 (18.6)
Median (IQR)	48.5 (31.0)	53.0 (29.5)
Range	19.0-89.0	18.0-98.0
Sex, n (%)		
Female	51 (51.0)	626 (57.1)
Male	49 (49.0)	470 (42.9)
Race, n (%)		
Asian	16 (16.0)	104 (9.5)
Black/African American	10 (10.0)	115 (10.5)
Native American	1 (1.0)	8 (0.7)
Pacific Islander	2 (2.0)	5 (0.5)
White	65 (65.0)	794 (72.5)
Mixed race	2 (2.0)	28 (2.6)
Other	4 (4.0)	41 (3.7)
Data missing	0 (0.0)	1 (0.1)
Ethnicity, n (%)		
Hispanic or Latino	6 (6.0)	86 (7.9)
Non-Hispanic or Latino	94 (94.0)	1006 (92.1)
Data missing	0 (0.0)	4 (0.4)
Smoking status, n (%)		
Never smoker	64 (66.0)	651 (60.2)
Current/former smoker	33 (34.0)	430 (39.8)
Data missing	3 (3.0)	15 (1.4)
BMI, kg/m^2		
Mean (SD)	28.4 (6.6)	29.5 (7.4)

AD, atopic dermatitis; BMI, body mass index; IQR, interquartile range; N, total treatment group; n, covariate sample size; SD, standard deviation.

BMI data were missing for 3 patients (3.0%) and 34 patients (3.1%) in the abrocitinib and systemic comparator therapy arms, respectively.

Table 3. Baseline Disease Characteristics for Patients Included in the Delayed-Onset Outcomes Analysis

	Abrocitinib N=100	Systemic Comparator Therapy N=1096
Duration of AD, mean (SD), years	19.2 (16.8)	14.6 (16.0)
%BSA involvement		
Mean (SD)	12.2 (14.5)	19.3 (19.0)
EASI score		
Mean (SD)	7.3 (9.1)	10.4 (10.6)
Global assessment of AD severity, n (%)		
Clear	3 (3.1)	47 (4.4)
Almost clear	17 (17.5)	97 (9.0)
Mild	11 (11.3)	142 (13.2)
Moderate	26 (26.8)	435 (40.3)
Severe	40 (41.2)	358 (33.2)
Data missing	3 (3.0)	17 (1.6)

%BSA, percentage of body surface area; AD, atopic dermatitis; EASI, Eczema Area and Severity Index; N, total treatment group; n, covariate sample size; SD, standard deviation.

%BSA involvement data were missing for 3 patients (3.0%) and 18 patients (1.6%) in the abrocitinib and systemic comparator therapy arms, respectively.

EASI score data were missing for 3 patients (3.0%) and 19 patients (1.7%) in the abrocitinib and systemic comparator therapy arms, respectively.

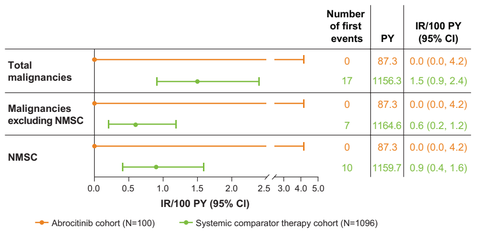
Acute-Onset Outcomes Analysis

- A total of 1084 exposures were included in the acute-onset outcomes analysis, including 88 exposures in the abrocitinib cohort (N=85; total exposure: 58.7 PY) and 996 exposures in the systemic comparator therapy cohort (N=889; 833.8 PY)
- Most patients in the acute-onset outcomes analysis were female and White across treatment cohorts
  - Demographics and baseline disease characteristics in the acute-onset outcomes analysis were defined based on exposures, and data were analyzed accordingly

Delayed-Onset Outcomes

- A total of 17 malignancies were reported in the systemic comparator cohort, including 7 events of malignancies (excluding NMSC) and 10 events of NMSC; no malignancy events were reported in the abrocitinib cohort during the study period (**Figure 2**)
  - IRs for all malignancy outcomes were numerically greater in the systemic comparator cohort versus the abrocitinib cohort with overlapping 95% CIs

Figure 2. Incidence Rates per 100 Patient-Years for Prespecified Delayed-Onset Safety Events of Interest



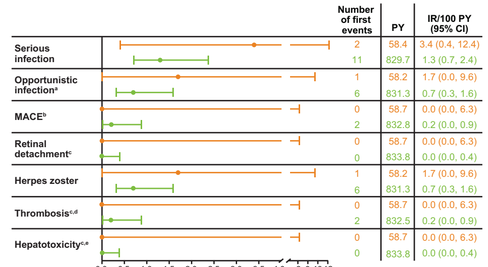
CI, confidence interval; IR, incidence rate; NMSC, nonmelanoma skin cancer; PY, patient-years.

Delayed onset events were included once cumulative exposure of ≥30 days was met.

Acute-Onset Outcomes

- IRs were numerically greater in the abrocitinib cohort versus the systemic comparator cohort during the study period for serious infection, opportunistic infection, and herpes zoster, and were greater in the systemic comparator cohort versus the abrocitinib cohort for MACE and thrombosis, with overlapping 95% CIs (**Figure 3**)
  - No events of retinal detachment or hepatotoxicity were reported in either cohort during the study period

Figure 3. Incidence Rates Per 100 Patient-Years for Prespecified Acute-Onset Safety Events of Interest



ATE, arterial thromboembolism; CI, confidence interval; DILI, drug-induced liver injury; DVT, deep vein thrombosis; IR, incidence rate; MACE, major adverse cardiovascular event; MI, myocardial infarction; PE, pulmonary embolism; PY, patient-years; TB, tuberculosis; VTE, venous thromboembolism.

[a]Includes serious and nonserious active TB.

[b]Includes MI, stroke, and cardiovascular death.

[c]Retinal detachment, ATE, and DILI event types were recoded as applicable for events reported into the Registry based on available data (eg, free text and supporting records) where aligned with case definitions.

[d]Defined as VTE (DVT, PE, and other VTEs) or ATE (peripheral ATEs, urgent peripheral arterial revascularization, peripheral ischemia or gangrene, and other ATEs).

[e]Includes DILI and other serious and nonserious hepatotoxicity events.

CONCLUSIONS

- No new safety signals and a low incidence of prespecified safety events of interest were observed in the abrocitinib cohort over 2 years; however, caution should be exercised when interpreting crude, unadjusted IRs
- These results align with the known safety profile of abrocitinib
- As the number of patients and exposures for abrocitinib are limited, the results shown are with relatively large variance, which may limit the interpretation of the data

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CONTACT INFORMATION

Contact Sampada Gandhi at sampada.gandhi@pfizer.com for questions or comments.

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