23 July 2026
EMADOC-1700519818-3384985
Human Medicines Division

Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Cibinqo

Abrocitinib

Procedure no: EMA/PAM/0000347917

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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Status of this report and steps taken for the assessment			
Current step[1]	**Description**	**Planned date**	**Actual Date**
☐	Start date	25 May 2026	25 May 2026
☐	CHMP Rapporteur AR	29 June 2026	24 June 2026
☐	CHMP comments	13 July 2026	n/a
☐	Updated CHMP Rapporteur AR	16 July 2026	n/a
☒	CHMP outcome	23 July 2026	23 July 2026

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1. Introduction

On 8 May 2026, the MAH submitted a completed paediatric study for Cibinqo, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

A short critical expert overview has also been provided.

The MAH does not propose an update of the product information.

2. Scientific discussion

2.1. Information on the development program

Cibinqo, which contains the JAK-inhibitor abrocitnib as active substance, was approved in EU on 09 Dec 2021 for the treatment of moderate-to-severe AD in adults who are candidates for systemic therapy. A Type II Variation to expand the indication to include adolescents with moderate-to-severe AD who are candidates for systemic therapy was submitted to EMA in May 2023. The MAH received a positive CHMP Opinion on February 22, 2025, and a EC Decision on March 21, 2024.

According to the line listing of all the studies included in the development program submitted by the MAH, Study B7451126 "Abrocitinib for Treatment of Atopic Dermatitis in the Real-World Dermatology Setting: Patient Characteristics, Disease Activity, and Clinical Outcomes" was not part of the development program.

2.2. Information on the pharmaceutical formulation used in the study

The abrocitinib formulation currently marketed in the US and used in the study is an oral tablet formulation: 50 mg, 100 mg and 200 mg film-coated tablet. This is also the authorized formulation for treatment of AD in the EU.

2.3. Clinical aspects

Introduction

The MAH submitted a final report for:

• Study B7451126 titled *"Abrocitinib for Treatment of Atopic Dermatitis in the Real-World Dermatology Setting: Patient Characteristics, Disease Activity, and Clinical Outcomes"*

Clinical study

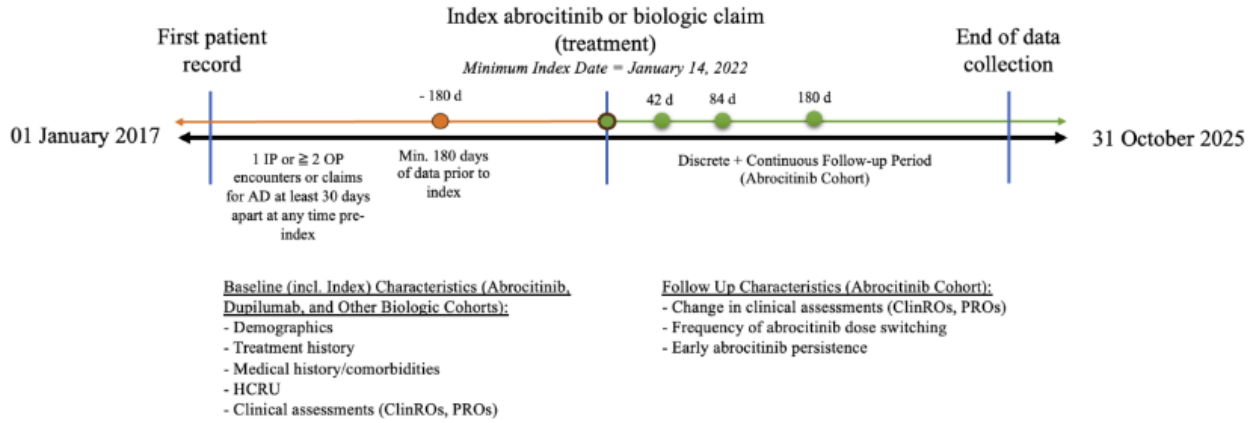
Study B7451126 - Abrocitinib for Treatment of Atopic Dermatitis in the Real-World Dermatology Setting: Patient Characteristics, Disease Activity, and Clinical Outcomes

Description

Study B7451126 was a retrospective cohort analysis of adolescent and adult patients aged 12 years and older with AD from the OMNY Health Platform between January 1, 2017 and October 31, 2025 who initiated abrocitinib or other biologics approved for the treatment of AD as confirmed by administrative claims data on or after January 14, 2022 or February 9, 2023 (date of abrocitinib US market approvals

for adults and adolescents, respectively) or the age- and drug-specific United States (US) Food and Drug Administration (FDA) approval date (see Figure 1).

Figure 1. Study Design



The first paid claim date is the index date for the study. Patients were observed with a variable follow up period to the first of (a) the end of their linked EHR-claims data during the overarching study period; (b) the initiation of an alternate advanced treatment approved for moderate to severe AD; or (c) loss to follow up due to treatment discontinuation.

Patients were assigned to a treatment cohort based on having a paid claim for a medication included in the study based on age- and AD-specific FDA approval dates. Three treatment groups were defined in this study for adolescent patients based on utilization of abrocitinib, dupilumab, or other biologics on or after February 9, 2023. By design, subjects could be assigned to one or more study groups and all subjects assigned to the Dupilumab Treatment cohort are also assigned to the Biologics Treatment Cohort.

As previously noted, the study included both adults and adolescents. This assessment report focuses specifically on the adolescent population.

Methods

Study participants

The study utilized a convenience sample of US-based real-world data that was extracted from the OMNY Health Platform. The OMNY Health Platform includes patients treated in Integrated Delivery Networks, Specialty Hospitals, and Specialty Provider groups, including specialty dermatology practice networks. The data are EHR-software agnostic and represent clinical encounters from a diverse mix of providers for care delivered in both inpatient and ambulatory care settings across the US.

Regardless of treatment cohort assignment, the following was required:

• Subjects had to have >= 1 inpatient (IP) or >= 2 outpatient (OP) claims or encounters at least 30 days apart at any time pre-index (January 1, 2017 to index) in the linked EHR-claims data with an ICD-10-CM diagnosis code for AD, defined as L20.0, L20.81, L20.82, L20.83, L20.84, L20.89, L20.9, L30.8, or L30.9. If outpatient events qualified the subject for the study, both events had to have been documented within the same data source (e.g., required to have 2 OP encounters in the EHR data or 2 OP encounters in the claims data, not 1 OP in claims and 1 OP in encounters).

• At least 1 claim or encounter dated a minimum of 180 days prior to index.

Patients were excluded if there was evidence of pregnancy or breastfeeding within 30 days prior to index or any form of active or latent tuberculosis, severe renal impairment or end-stage renal disease (ESRD), or rheumatoid arthritis in the 365 days prior to index. Patients were also excluded from the Dupilumab and Other Biologics Treatment groups if they had a paid claim for abrocitinib prior to the age-specific FDA approval date.

Objectives

The primary objective was to characterize patients with linked electronic health records (EHR) and open claims data initiating abrocitinib or biologics for the treatment of AD, reporting abrocitinib and dupilumab individually ("Abrocitinib Treatment Cohort" and "Dupilumab Treatment Cohort", respectively), and combined for dupilumab, tralokinumab, lebrikizumab, and nemolizumab ("Other Biologics Cohort"). This included reporting on the following:

1. Demographic and encounter characteristics at baseline

2. Patient medical history and co-morbidities documented in the EHR or paid claims in the pre-index period

3. Treatment and medication history based on paid claims in the pre-index period

4. All-cause and AD-specific healthcare resource utilization (HCRU) and charges in the pre-index period

5. Disease severity among patients with at least one Clinician Reported Outcome (ClinRO) (i.e., Investigator Global Assessment [IGA], percent Body Surface Area [BSA]) or Patient Reported Outcome (PRO) (i.e., Itch Numerical Rating Scale [NRS]).

6. Among patients with at least one ClinRO or PRO at index, count how many patients have a corresponding follow up measure at Week 6, 12, and 16 post-index.

Secondary objectives included describing the directionality of dose change and early persistence of medication use among patients in the Abrocitinib Treatment Cohort. Where follow up data was available, exploratory objectives included characterizing change in disease severity as measured by each ClinRO and PRO among patients designated as moderate-to-sever at baseline among the Abrocitinib Treatment Cohort at 6 and 12 weeks post-index.

Outcomes/endpoints

In addition to the characterization of patient's demographics, medical history, treatment history, and HCRU, the study sought to evaluate AD disease severity outcomes as they were available in the structured EHR data. This included the following measures: IGA, Itch NRS, Percent BSA, and affected body region. The availability of these outcome measures was assessed at Baseline and 6, 12, and 16 weeks post-index. For patients with measures, disease severity and affected body region was assessed at Baseline. Among patients with measures at Baseline and 6 or 12 weeks, change in disease severity or affected body region was calculated.

Sample size

A total of 1,606 adolescent patients met all eligibility criteria for the study. 2.1% (34) of the adolescent patients were in the Abrocitinib Treatment Cohort. Of the 34 qualifying adolescent patients, 4 (11.8%) had at least one ClinRO or PRO at index and were included in subsequent measures-related analyses and exploratory objectives.

The Dupilumab Treatment Cohort included 1,538 patients and represents a subset of the Other Biologics Treatment Cohort which included 1,572 patients.

This study utilized a convenience sample from real-world observational data. The intent of this study was descriptive, and each analysis used the observed data from all patients who met analysis-specific criteria. Formal sample size calculations were not applicable to this study and were not performed as no specific hypotheses were being tested, nor any prespecified precision being sought around point estimates.

Statistical Methods

An interim analytic file with data from January 1, 2017 to June 30, 2025 was used to produce preliminary results. A final analytic file with data from encounters and claims with service dates from January 1, 2017 to October 31, 2025 was used for all final analyses. All analyses were conducted in R and Python.

Summary statistics were produced to achieve all study objectives. No statistical testing was conducted as part of this study. Only descriptive summaries were estimated. P values were not generated as part of these analyses. Categorical variables were summarized as frequency and proportion of the study cohorts or subgroup among non-missing values, with missingness separately reported. Continuous variables were reported as mean, standard deviation, median, interquartile range, minimum, and maximum. HCRU and cost outcomes were calculated as per patient per year (PPPY) along with 95% Poisson exact confidence intervals. No statistical testing was to be conducted as part of this study.

Results

Demographics

Abrocitinib Treatment Cohort

50% (n=17) of adolescent patients were female with a mean age of 15.35 (SD = 1.47) years. Among those with race reported, White was the predominant race (40.7%, n=7) and the remaining race distribution in rank order was as follows: Unknown (33.3%, n=9), Other (11.1%, n=3), Black or African American (7.4%, n=2), and Asian patients (7.4%, n=2). About half of patients were Not Hispanic or Latino (44.4%, n=12), one-fifth were Hispanic or Latino (18.5%, n=5), and Unknown was selected for one-third (37.0%, n=10). Body mass index (BMI) was available for 17.7% (n=6) of the adolescent population; these patients had an average BMI of 29.95 (SD=6.29) and were mostly Obese (66.7%, n=4)

Dupilumab Treatment Cohort

57.7% (n=887) of adolescent patients were female with a mean age of 14.82 (SD = 1.71) years. Among those with race reported, White was the predominant race (34.8%, n=479) and the remaining race distribution in rank order was as follows: Unknown (30.6%, n=420), Black or African American (19.4%, n=266), Other (7.3%, n=100), Asian patients (6.5%, n=89), and American Indian or Alaska Native (1.5%, n=21). About half of patients were Not Hispanic or Latino (44.3%, n=609) and 10.3% (n=141) were Hispanic or Latino. Unknown ethnicity was selected for all remaining patients (45.5%, n=625). BMI was available for one-third (34.7%, n=533) of the adolescent population; these patients had an average BMI of 23.38 (SD=6.47).

Other Biologics Treatment Cohort

57.9% (n=910) of adolescent patients in the Other Biologics Treatment Cohort were female with a mean age of 14.83 (SD = 1.71) years. Among those with race reported, White was the predominant

race (35.0%, n=491) and the remaining race distribution in rank order was as follows: Unknown (30.8%, n=433), Black or African American (19.3%, n=271), Other (7.1%, n=100), Asian patients (6.3%, n=89), and American Indian or Alaska Native (1.5%, n=21). About half of patients were Not Hispanic or Latino (44.1%, n=620) and 10.2% (n=143) were Hispanic or Latino. Unknown ethnicity was selected for all remaining patients (45.7%, n=642). BMI was available for one-third (34.3%, n=539) of the adolescent population; these patients had an average BMI of 23.37 (SD=6.44)

Comorbidities

Abrocitinib Treatment Cohort

Two-thirds (67.7%, n=23) of adolescent patients in the Abrocitinib Treatment Cohort had a history of Atopic and Allergic Conditions and half (52.9%, n=18) had a history of Metabolic Disorders. A little more than one-third of all patients had also reported Immune-Mediated Conditions (41.2%, n=14), Mental Health and Substance Use Conditions (38.2%, n=13), and Skin Infections (35.3%, n=12), while one-quarter of the cohort had Ophthalmic Conditions (26.5%, n=9). Less than 10% of patients in the adolescent Abrocitinib Treatment Cohort previously experienced Bone Health issues or Cardiovascular Disease, and no patients had any documented Circulatory Diseases. 50% (n=17) of patients in the cohort specifically had a history of allergic rhinitis and overweight/obesity, 41.2% had asthma, 35.3% (n=12) had food allergies, and 26.5% (n=9) had anxiety or conjunctivitis keratitis

Dupilumab Treatment Cohort

Three-quarters (75.2%, n=1,157) of adolescent patients in the Dupilumab Treatment Cohort had a history of Atopic and Allergic Conditions. One-third to two-fifths of all patients had other key comorbidities such as Immune-Mediated Conditions (40.2%, n=618), Skin Infections (39.6%, n=609), Mental Health and Substance Use Conditions (38.0%, n=585), and Metabolic Disorders (34.3%, n=528), while slightly more than one-quarter of the cohort had Ophthalmic Conditions (29.7%, n=456). Less than 20% of patients in the adolescent Dupilumab Treatment Cohort previously experienced Bone Health issues (17.8%, n=273), and less than 5% had any history of Cardiovascular Disease (2.6%, n=40) or Circulatory Diseases (0.3%, n=5). More than half (59.0%, n=908) of patients in the cohort overall had a history of allergic rhinitis, 46.8% (n=719) had asthma, 34.3% (n=527) had food allergies, 32.3% (n=496) had overweight/obesity, and 28.7% (n=442) had conjunctivitis keratitis

Other Biologics Treatment Cohort

Three-quarters (75.3%, n=1,183) of adolescent patients in the Other Biologics Treatment Cohort had a history of Atopic and Allergic Conditions. One-third to two-fifths of all patients had other key comorbidities such as Immune-Mediated Conditions (40.0%, n=629), Skin Infections (39.7%, n=624), Mental Health and Substance Use Conditions (38.2%, n=600), and Metabolic Disorders (34.5%, n=542), while slightly more than one-quarter of the cohort had Ophthalmic Conditions (29.3%, n=460). Less than 20% of patients in the adolescent Biologics Treatment Cohort previously experienced Bone Health issues (17.8%, n=280), and less than 5% had any history of Cardiovascular Disease (2.5%, n=40) or Circulatory Diseases (0.3%, n=5). More than half (59.0%, n=928) of patients in the cohort overall had a history of allergic rhinitis, 46.4% (n=730) had asthma, 34.1% (n=536) had food allergies, 32.4% (n=509) had overweight/obesity, and 28.3% (n=445) had conjunctivitis keratitis

Treatments

Abrocitinib Treatment Cohort

About half of adolescent patients had previously used Systemic AD Treatments (52.9%, n=18), and almost three-quarters had previously used Topical AD Treatments (70.6%, n=24).

Dupilumab Treatment Cohort

More than one-third of adolescent patients had previously used Systemic AD Treatments (37.7%, n=579), and half had previously used Topical AD Treatments (53.3%, n=820).

Other Biologics Treatment Cohort

More than one-third of adolescent patients had previously used Systemic AD Treatments (37.9%, n=596), and half had previously used Topical AD Treatments (53.5%, n=841).

HCRU

Abrocitinib Treatment Cohort

Of adolescent patients in the Abrocitinib Treatment Cohort with all-cause hospital admissions (n=5) the mean PPPY charges incurred was $242 (SD = $275). There were 3 adolescents that had an AD-related hospitalization. 5 adolescent patients had an AD-related emergency or urgent care visit.

Dupilumab Treatment Cohort

Of adolescent patients in the Dupilumab Treatment Cohort with all-cause hospital admissions (n=213) the mean PPPY charges incurred was $989 (SD=$3,037). There were 42 adolescents that had an AD-related hospitalization. 254 adolescent patients had an AD-related emergency or urgent care visit.

Other Biologics Treatment Cohort

Of adolescent patients in the Other Biologics Treatment Cohort with all-cause hospital admissions (n=217) the mean PPPY charges incurred was $996 (SD=$3,011). There were 43 adolescents that had an AD-related hospitalization. 261 adolescent patients had an AD-related emergency or urgent care visit.

Baseline Outcome Measures Data Availability Disease Severity (All Cohorts)

In the Abrocitinib Treatment Cohort, 11.8% (n=4) of the adolescent patients had a ClinRO or PRO documented at baseline. All four patients were categorized as having moderate to severe AD based on one or more of the measures documented. 50% (n=2) of the patients were characterized as moderate to severe AD based on Itch NRS, 75% (n=3) were characterized as moderate to severe AD based on BSA, and 75% (n=3) were characterized as moderate to severe AD based on IGA.

In the Dupilumab Treatment Cohort, 10.9% (168) of the adolescent patients had a ClinRO or PRO documented at baseline. 75.0% (n=126) patients were categorized as having moderate to severe AD based on one or more of the measures documented. 68.0% (n=87) of the patients were characterized as moderate to severe AD based on their Itch NRS, 68.5% (n=111) were characterized as moderate to severe AD based on BSA, and 64.3% (n=81) were characterized as moderate to severe AD based on IGA.

In the Other Biologics Treatment Cohort, 11.0% (n=1,572) of the adolescent patients had a ClinRO or PRO documented at baseline. 75.6% (n=131) patients were categorized as having moderate to severe AD based on one or more of the measures documented. 68.4% (n=91) of the patients were characterized as moderate to severe AD based on their Itch NRS, 68.7% (n=114) were characterized

as moderate to severe AD based on BSA, and 64.3% (n=83) were characterized as moderate to severe AD based on IGA.

Post-Index Measures Availability

Dupilumab Treatment Cohort

Among adolescents in the Dupilumab Treatment Cohort, at Week 6, 10.2% (n=13) of the adolescent patients with Itch reported at baseline had a follow up Itch score. A slightly lower proportion (7.8% (n=10) had a follow-up Itch at Week 12, while 10.2% (n=13) had a Week 16 Itch score. A similar pattern was observed for IGA and BSA.

Other Biologics Treatment Cohort

Among adolescents in the Other Biologics Treatment Cohort, at Week 6, 11.3% (n=15) of the adolescent patients with Itch reported at baseline had a follow up Itch score. Nearly this same proportion had a follow up Itch at 16 weeks, but at the 12-week timepoint only 8.3% (n=11) of patients had a follow up Itch documented. Similar patterns were observed for IGA

and BSA.

Abrocitinib Treatment Cohort

Among adolescents in the Abrocitinib Treatment Cohort, at week 6 only one of the two adolescent patients with Itch reported at baseline had a follow up Itch score. Similarly, at week 12, only one of the two patients with Itch reported at baseline had a follow up Itch score at this timepoint. No patients had a 16-week post-index measure. The same was observed for IGA and BSA.

Safety results

Safety was not examined in this study.

The MAH´s conclusions

This was the first study to characterize US-based adolescents treated with abrocitinib in real world EHR data linked to open claims. More adolescents received dupilumab and/or other biologics during the observation period than received abrocitinib (1,572 vs. 34). Across all three cohorts, patients tended to be female and with an average age of 15 years. Most patients taking these medications were White, but the proportion of patients in the Dupilumab and Other Biologics Treatment Cohorts who were Black or African American was double that reported in the Abrocitinib Treatment Cohort (19.3% vs. 19.4% vs 7.4%, respectively). Otherwise, the demographic characteristics, prior co-morbidities, treatment histories, and HCRU prior to index were all relatively similar across all cohorts.

Proportionally, the availability of measures at baseline were nearly identical across all three cohorts (Abrocitinib, 11.8% vs. Dupilumab, 10.9% vs. Other Biologics, 11.0%). This trend continued in the post-index period, with at most one-tenth of patients in the cohorts having any follow-up measure reported at 6, 12, or 16 weeks post-index. This indicates that documentation of clinical measures of disease severity among these patients was limited, even considering that nearly half of patients were treated in Dermatology Specialty Practices where their EHR makes such capture reasonably easy and straightforward. This creates a challenge when trying to replicate clinical trial outcomes using real world data.

Discussion on clinical aspects

The MAH submitted the results for Study B7451126, in accordance with Article 46 of Regulation (EC) No1901/2006.

Study B7451126 was a retrospective cohort analysis of adolescent and adult patients aged 12 years and older with AD from the OMNY Health Platform between January 1, 2017 and October 31, 2025 who initiated abrocitinib or other biologics approved for the treatment of AD as confirmed by administrative claims data on or after January 14, 2022 or February 9, 2023 (date of abrocitinib US market approvals for adults and adolescents, respectively) or the age- and drug-specific US FDA approval date.

Three treatment groups were defined in this study for adolescent patients based on utilization of abrocitinib, dupilumab, or other biologics. A total of 1,606 adolescent patients met all eligibility criteria for the study. Only 2.1% (34) of the adolescent patients were in the Abrocitinib Treatment Cohort. Thus, the interpretation of data in the adolescent Abrocitinib group should be made with caution.

The final analysis cohort consisted of 401 patients, selected from an initial pool of 585 individuals identified in linked EHR-claims data who had a paid claim for abrocitinib on or after their age-appropriate FDA-approval date, a documented history of AD, and lacking non-qualifying contraindications in their medical history.

About half of adolescent patients in the Abrocitinib Treatment Cohort had previously used Systemic AD Treatments (52.9%, n=18). In the Dupilumab Treatment Cohort and the Other Biologics Treatment Cohort these rates were 37.7% (n=579) and 37.9% (n=596), respectively.

A very small proportion of patients had ClinROs or PROs captured at baseline or in the designated 6 week, 12 week, and 16 week timepoints. Among adolescents in the Abrocitinib Treatment Cohort, at week 6 only one of the two adolescent patients with Itch reported at baseline had a follow up Itch score. In the Dupilumab Treatment Cohort and the Other Biologics Treatment Cohort these rates were 10.2% (n=13) and 11.3% (n=15), respectively.

As already stated by the MAH, the findings from this study may not apply to the entire AD patient population, nor may they be generalizable to those treated outside the OMNY Health network since the data is exclusively sourced from US-based practices. Data interpretation is further constrained by statistical limitations.

Safety was not examined in this study.

Overall, the benefit-risk of upadacitinib is unchanged. No update to the Summary of Product Characteristics is proposed by the MAH, which is endorsed.

3. Rapporteur's overall conclusion and recommendation

The final results of the non-interventional retrospective cohort Study B7451126, characterizing patients initiating abrocitinib, dupilumab, and other biologics for the treatment of moderate-to-severe atopic dermatitis, have been reported. The assessment of the benefit-risk profile of abrocitinib is not affected by this study. The MAH has not suggested any update to the Summary of Product Characteristics based on the performed study, which is supported by the Rapporteur.

☒ **Fulfilled:**

No regulatory action required.