Patient profile and treatment characteristics of early ritlecitinib initiators in the US

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INTRODUCTION

- Alopecia Areata (AA) is an autoimmune disease characterized by unpredictable, non-scarring hair loss associated with psychosocial comorbidities and quality of life impairment.[1,2,3]
- In June 2023, the FDA approved ritlecitinib (50mg) for treatment of severe AA in adults and adolescents 12 years and older. In the ALLEGRO phase 2b/3 randomized, placebo-controlled clinical trial, ritlecitinib 50mg demonstrated a significantly greater proportion of patients achieving 80% or more scalp hair coverage at 24 weeks compared to placebo.[4]
- However, with the recent FDA approval of ritlecitinib, there is a need to better understand how practitioners are integrating ritlecitinib into their current treatment landscape for AA.

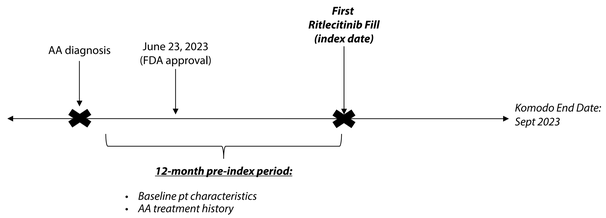
OBJECTIVE

- The objective of this study was to examine characteristics of patients who were prescribed ritlecitinib in real-world settings within the first three months following approval.

METHODS

- This was a retrospective observational study analyzing de-identified data from the **Komodo Healthcare (TM) database**.
- **Komodo** is comprised of open and closed medical and pharmacy claims for more than 330M lives in the US **(Jan 2016 to Sept 19, 2023)** - Commercial, Medicaid, and Medicare coverage.
- The index date was defined as the date of the first prescription for ritlecitinib.
- Patient's demographic and clinical characteristics were evaluated at index date and during the 12-month pre-index period. AA treatment history was assessed over the 12-month pre-index period
- Analyses were descriptive only and stratified by age groups i.e., (1) 12 to 17 years and (2) ≥18 years

Figure 1. Study design*

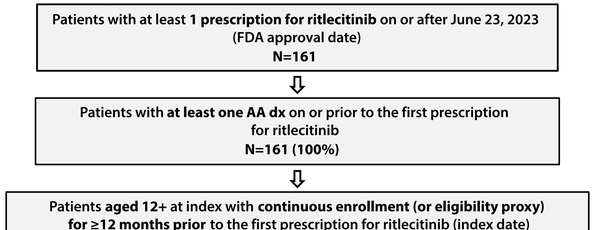


*For illustration purposes, the calendar axis may not be proportional

RESULTS

- A total of 150 patients met the inclusion and exclusion criteria and were included in this study (**Figure 2**).

Figure 2. Sample Selection Flowchart



- Adolescents accounted for more than half of the patients initiating ritlecitinib (**Table 1**).
- Overall, 31.3% of patients had a diagnosis for AT/AU as of the closest diagnosis before or on the index date (adolescent: 36.7%; adults: 25.4%).
- More than half of initiators were female and 78.0% were commercially insured.
- The most common prescribers were dermatologists.

Table 1. Demographic characteristics

Characteristics	All patients N = 150	12 to 17 years old N=79	18+ years old N=71
AA subtype (closest dx prior to ritlecitinib)			
AT/AU	47 (31.3%)	29 (36.7%)	18 (25.4%)
AT	22 (14.7%)	15 (19.0%)	7 (9.9%)
AU	25 (16.7%)	14 (17.7%)	11 (15.5%)
Ophiasis	1 (0.7%)	1 (1.3%)	0 (0.0%)
Other alopecia areata	51 (34.0%)	20 (25.3%)	31 (43.7%)
Alopecia areata, unspecified	56 (37.3%)	33 (41.8%)	23 (32.4%)
Sex			
Male	72 (48.0%)	42 (53.2%)	30 (42.3%)
Female	78 (52.0%)	37 (46.8%)	41 (57.7%)
Insurance type (pharmacy benefit)			
Missing/unknown	3 (2.0%)	2 (2.5%)	1 (1.4%)
Commercial	117 (78.0%)	61 (77.2%)	56 (78.9%)
Medicaid	25 (16.7%)	16 (20.3%)	9 (12.7%)
Medicare	5 (3.3%)	0 (0.0%)	5 (7.0%)
Most common prescriber specialty			
Dermatology specialty	108 (72.0%)	56 (70.9%)	52 (73.2%)
Physician assistant	20 (13.3%)	8 (10.1%)	12 (16.9%)

- During the 12 months before index date, 11.3% of patients had a diagnosis recorded for one of the selected autoimmune disorders (**Table 2**).
  - 5.1% of patients in the adolescent's cohort and 18.3% of patients in the adult's cohort
- Overall, approximately 1 in 4 patients had a diagnosis for at least one of the selected atopic disorders during the 12 months before index date.
  - The most common atopic disorder observed among adults was atopic dermatitis (11.3%) followed by asthma (8.5%).
  - Among adolescents, allergic rhinitis (15.2%) was the most common atopic disorder observed followed by atopic dermatitis (12.7%).
- During the 12 months pre-index period, a total of 20.7% patients had at least one diagnosis for mental/emotional disorders.
  - Anxiety and major depressive disorders were observed in 11.4% and 8.9% of adolescents and 16.9% and 11.3% of adults, respectively.

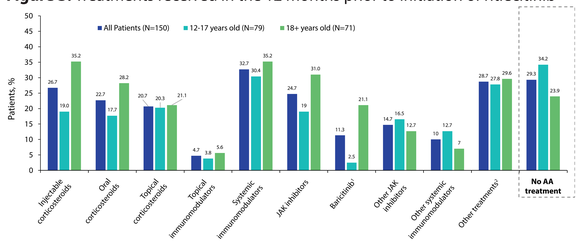
Table 2. Comorbidities observed in the 12 months prior to index date

Characteristics	All patients N = 150	12 to 17 years old N=79	18+ years old N=71
Other selected autoimmune disorders*	**17 (11.3%)**	**4 (5.1%)**	**13 (18.3%)**
Ankylosing spondylitis	1 (0.7%)	0 (0.0%)	1 (1.4%)
Diabetes mellitus	5 (3.3%)	0 (0.0%)	5 (7.0%)
Hashimoto's disease	4 (2.7%)	0 (0.0%)	4 (5.6%)
Lupus erythematosus	1 (0.7%)	1 (1.3%)	0 (0.0%)
Psoriasis	1 (0.7%)	0 (0.0%)	1 (1.4%)
Vitiligo	5 (3.3%)	3 (3.8%)	2 (2.8%)
Atopic disorders*	**35 (23.3%)**	**20 (25.3%)**	**15 (21.1%)**
Allergic rhinitis	13 (8.7%)	12 (15.2%)	1 (1.4%)
Asthma	10 (6.7%)	4 (5.1%)	6 (8.5%)
Atopic dermatitis	18 (12.0%)	10 (12.7%)	8 (11.3%)
Conjunctivitis	1 (0.7%)	0 (0.0%)	1 (1.4%)
Mental Health	**31 (20.7%)**	**16 (20.3%)**	**15 (21.1%)**
Attention deficit hyperactivity disorder	11 (7.3%)	10 (12.7%)	1 (1.4%)
Anxiety disorders	21 (14.0%)	9 (11.4%)	12 (16.9%)
Major depressive disorder	15 (10.0%)	7 (8.9%)	8 (11.3%)

*Crohn's disease, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, sjogren's syndrome (Sicca syndrome), ulcerative colitis, were also assessed but not reported as no patients had a diagnosis recorded for these conditions during the 12 month pre-index period.

- Among adults, during the 12 months pre-index period, 1 in 3 patients received injectables corticosteroids, systemic immunomodulators, and JAK inhibitors (baricitinib was used in 21.1% of patients) (**Figure 3**).
- Among adolescents, systemic immunomodulators was the most commonly used medications (30.4%), followed by other treatments (27.8%) and topical corticosteroids (20.3%).
- The mean time between the last day of supply of the prior medication and the start of ritlecitinib was approximately 51 days for both adolescent and adults (not reported).
- A total of 23.9% of adults and 34.2% of adolescents did not receive any of the selected AA treatments during the 12 months pre-index period.

Figure 3. Treatments received in the 12 months prior to initiation of ritlecitinib



‡ Baricitinib is only approved in patients 18 and over. † Other treatments included: Minoxidil oral/topical, Bimatoprost, Narrow band UVB, Excimer laser, PUVA
Use of contact/allergen immunotherapy was assessed but not reported as no patients received these treatments during the pre-index period

CONCLUSIONS

- In the first 3 months following the US approval, ritlecitinib was prescribed to a broad range of patients; including adolescent and adults; those with and without prior treatments; and those with and without various comorbidities.
  - Three quarters of patients received other treatments for AA in the prior 12 months, which may indicate that such therapies were suboptimal in meeting patient's treatment goals.
  - Nearly 30% of patients had no evidence of prior AA treatment in the 12 months preceding their first ritlecitinib fill, suggesting that ritlecitinib may provide patients with new opportunities to (re)engage in care.
- As ritlecitinib continues to be integrated into clinical practice, additional exploration into uptake and clinical outcomes will be critical to evaluate the changing treatment landscape of AA.

LIMITATIONS

- These are initial results with a small sample size; further exploration with larger sample size is required to better inform the treatment landscape.
- Most patients who were prescribed ritlecitinib were identified from open claims. Proxy for enrollment was used but we cannot confirm we have full visibility on the treatments received by the patients.
- There is no disease severity information in Komodo and no information to confirm reasons for which a medication was prescribed.
- The study sample consisted primarily of privately insured employees and their dependents. Accordingly, results may not be generalizable to the overall population of patients with AA in the US.

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DISCLOSURES

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SK Kurosky, L Takiya, G Bell, Y-C Lee, and G Gauthier are employees and may hold stock or stock options in Pfizer. K Hanson is consultant for Pfizer.